Government of Botswana
Ministry of Health and Wellness

BOTSWANA POOLED PROCUREMENT REPORT:

Learning from Global, Regional and Country Experiences

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List of Abbreviations and Acronyms

ACAME	L'Association Africaine des Centrales d'Achats de Médicaments Essentiels
ACS	African Collaborative for Health Financing Solutions
ART	Antiretroviral therapy
ARV	Antiretroviral
AUC	African Union Commission
BoMRA	Botswana Medicines Regulatory Authority
CDC	The Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CMS	Central Medical Stores
COMESA	Common Market for Eastern and Southern Africa
COVID-19	Coronavirus Disease of 2019
EAC	East African Community
ECDS	Eastern Caribbean Drug Service
EU	European Union
GCC	Gulf Cooperation Council
GDF	Global Drug Facility
GDP	Gross Domestic Product
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GHSC	Global Health Supply Chain Program
GPP	Good Pharmaceutical Procurement
GoB	Government of Botswana
MoHW	Ministry of Health and Wellness
MSD	Medical Stores Department
NAHPA	National AIDS and Health Promotion
NASCOD	National Standing Committee on Drugs
NSF	National HIV and AIDS Response Strategic Framework
PAHO	Pan American Health Organization
PLHIV	Persons living with HIV
PPADB	Public Procurement and Asset Disposal Board
PPM	Pooled Procurement Mechanism
PSM	Procurement and Supply Management
RFF	Regional Integration Facilitation Forum
SACU	Southern African Customs Union
SADC	Southern African Development Community
SAPAM	Southern African Programme on Access to Medicines and Diagnostics
SDG	Sustainable Development Goal
SPPS	SADC Pooled Procurement Services
SWOT	Strengths, weaknesses, opportunities, threats
TLD	Tenofovir/lamivudine/dolutegravir
TFTA	Tripartite Free Trade Area

TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWG	Technical working group
UHC	Universal health coverage
UMIC	Upper-middle income country
UNAIDS	United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UNICEF	The United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organisation

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Executive Summary

Background

As part of its journey towards attaining universal health coverage (UHC), the Government of Botswana (GoB) has committed to ensuring access to safe, effective, quality, and affordable essential medicines and medical supplies for all its citizens. Medicine procurement is an important component of an effective medicines supply system, and, therefore, a major determinant in the quality of health services. However, the interrupted availability of essential medicines and commodities remains a major challenge affecting Botswana's health system, with stockouts and shortages impacting service delivery across the country. The GoB has set ambitious goals of 95 percent of people living with HIV (PLHIV) being diagnosed, ensuring that at least 95 percent of diagnosed PLHIV are on antiretroviral (ARV) treatment, and achieving viral load suppression for at least 95 percent of those on treatment by 2025. These targets can only be achieved through a reliable ARV supply and laboratory commodities, thereby ensuring that PLHIV have uninterrupted access to treatment across different levels of care. Pooled procurement of medicines is one approach for ensuring a consistent and sustainable supply of appropriate medicines at the national and district levels. Moreover, it is increasingly regarded globally as an efficient strategy to resolve challenges such as high medicine prices, poor quality, and other bottlenecks generally associated with procurement and supply chains of essential medicines and medical supplies.

Objective

This report aims to describe and analyze existing global and regional pooled procurement mechanisms to health system leaders and policymakers to facilitate a complete evaluation of the benefits of pooled procurement.

This report also examines the local procurement modalities to understand specific contextual considerations to guide the GoB and generate recommendations that inform policy decisions on shaping or adopting pooled procurement mechanism modalities.

Summary of Main Points

The following is a summary of the main points presented in this paper:

- *Pooled procurement is a process.* Conceptual frameworks such as the "World Health Organization (WHO) levels of pooled procurement framework" describe pooled procurement illustrate it as a distinct mechanism. However, in practice, pooled procurement needs to be approached as a continuum and understanding that progress may be iterative.
- *Pooled procurement requires an enabling environment*. Based on the reviewed country experiences, choosing to participate in regional pooled procurement will necessitate policy and regulatory re-alignment.
- *Regional pooled procurement mechanisms require a sustained commitment from member states.* A foundational premises for pooled procurement is that it creates a new market dynamic (monopsony) where power shifts to the buyer through demand aggregation. To reap

the benefits of this changing market dynamic, countries cannot engage in pooled procurement mechanisms as a one-off.

- *Differentiating between the ownership and administrative structures of regional and global mechanisms is critical to its success.* The examples in this report demonstrate a distinct difference in the setup of global versus regional pooled mechanisms. The mechanisms 'ownership' differentiates regional, which are owned by participating member states, and global mechanisms, owned and run out of a single global organization. In turn, this difference is crucial to how the mechanism is administered. A global organization has the structure in place to staff a pooled mechanism, while regional pooled mechanisms must figure out how to fund and set up a secretariat.
- *Technical support to countries is required to engage in pooled procurement*. One vital function of a pooled procurement mechanism should be to assess the differential capacity among countries and build all countries up to an agreed level.
- *Pooled procurement increases country access to essential medicines and supplies but does not solve in-country distribution challenges*. The literature emphasizes that one of the benefits of pooled procurement mechanisms is the increased availability of quality essential medicines at lower prices.

Key Takeaways and Considerations for Botswana

Interest and political will exist in-country to pursue pooled procurement. Implementing the following structures is necessary for Botswana to benefit from the joint purchasing approach and produce a successful and sustainable system.

- Educating stakeholders and the public on pooled procurement is critical because it adds political and economic dimensions. Advocacy is required to address these dimensions while planning for collaboration. GoB and other supportive international and local capacity-building organizations should take the initiative to educate stakeholders and the public on the concept to prevent misunderstandings that might create opposition to the process.
- The Ministry of Health and Wellness (MoHW) should work with partners to strengthen the capacity of the Central Medical Stores' (CMS) on forecasting and quantification; supplier performance assessment and increased collaboration; and information sharing.
- The Botswana Medicines Regulatory Authority (BoMRA) should harmonize the Essential Medicines Lists and Standard Treatment Guidelines with those of other member states to attain a wider range of products and initiate pooled procurement.
- Use existing national procurement management capacity and skills that will transfer and build support to the joint purchasing mechanism.
- Strengthening legal and regulatory statutes will ensure that the government earmarks adequate funds for the purchase of medicines. These legal provisions can take the form of a) mandated budget lines; b) specific allocations "ring-fenced"; or c) protected funds for medicines procurement.
- Implementing a detailed study will assess the current capacity of local manufacturers to address needs for pooled procurement in terms of medicine selection, volume, quality, and

identifying their potential role in regional pooled procurement of medicines and mapping the process.

- Signing a contractually binding agreement among the member states specifically for implementing regional pooled procurement will ensure organizational commitment.

1 Introduction

1.1 Background information

Providing quality health care is one of the Government of Botswana's (GoB) top priorities. However, the interrupted availability of essential medicines and commodities remains a challenge affecting Botswana's health system,[1] with stockouts and shortages impacting service delivery across the country. It is critical to ensure consistent access to essential medicines and commodities, especially considering Botswana's commitment to attain and maintain HIV/AIDS epidemic control[2] and to respond to the rising burden of non-communicable diseases such as cancer, diabetes, and cardiovascular diseases. The GoB has set ambitious goals achieving a diagnosis rate of at least 95 percent of persons living with HIV (PLHIV); ensuring that at least 95 percent of diagnosed PLHIV are on antiretroviral (ARV) treatment; and achieving suppression of viral load for at least 95 percent of those on treatment by 2025.[3] These targets can only be achieved through a reliable ARV supply and laboratory commodities, thereby ensuring that PLHIV have uninterrupted access to treatment across different levels of care.

While Botswana's total health expenditure is steadily increasing, there are concerns that the quality of services[4] and essential health outcomes do not align with the level of investment in the sector.[5] Efficiency is a priority area in the reform of Botswana's health care system. As articulated in Botswana's National Development Plan 11 (NDP 11), the third National HIV and AIDS Response Strategic Framework (NSF III): (2018/9–2022/3) ensures value for money is included in the HIV/AIDS response and the health sector broadly. Increasing technical and allocative efficiencies is critical both for sustaining the HIV/AIDS response and ensuring the financial sustainability of the overall health sector.

The African Collaborative for Health Financing Solutions (ACS) - a five-year (2017-2022) USAID-funded project aimed at advancing universal health coverage (UHC) in sub-Saharan Africa (SSA) - supported the GoB through the National AIDS and Health Promotion Agency (NAHPA) and the Ministry of Health and Wellness (MoHW.) The work aimed to implement a series of health financing solutions ensuring financial protection for attaining UHC and move toward sustaining the HIV/AIDS epidemic control. Among others, ACS provided support on best practices to support the realization of efficiency gains in Botswana to address inefficiencies in the health sector, particularly within the HIV/AIDS response.

As part of the United States Government (USG) support to the GoB through the United States Agency for International Development (USAID), ACS facilitated multi-stakeholder engagements

[1] Masisi, Mokgweetsi. "State of the Nation Address 2019." Mmegi Online, November 18, 2019. http://BoMRA.mmegi.bw/index.php?aid=83528&dir=2019/november/18.

[2] Avert. "HIV and AIDS in Botswana." *Avert* (blog), April 23, 2020. https://BoMRA.avert.org/professionals/hiv-around-world/sub-saharan-africa/botswana"

[3] ibid

[4] Johnson, Carleen Stoskopf, and Leiyu Shi. *Comparative Health Systems*. Jones & Bartlett Learning, 2017.

[5] Seitio-Kgokgwe, et al "Assessing Performance of Botswana's Public Hospital System: The Use of the World Health Organization Health System Performance Assessment Framework." *International Journal of Health Policy and Management* 3, no. 4 (September 1, 2014): 179–89. https://doi.org/10.15171/ijhpm.2014.85.

to identify priority interventions for maximizing efficiency gains in Botswana's health care system. Through this support, which aimed at fostering an inclusive sustainable financing dialogue, the HIV/AIDS Sustainable Financing Technical Working Group (TWG) agreed on priority actions to aid the health sector in increasing technical efficiencies. Given the number of resources spent on procuring medicines and medical supplies, one of the priority areas identified was facilitating a process through which the government could consider pooled procurement mechanisms to generate cost savings from reduced unit costs and ensure improved availability of essential medicines and related supplies. With the MoHW reporting a reduction in average availability of essential and necessary medicines at public health facilities from 89 percent in 2015 to 84.7 percent against a 97 percent target in 2018[6], improvement in this area is the ministry's priority. By September 2019, Botswana had 98.8 percent availability of the optimized HIV treatment regimen TLD (tenofovir/lamivudine/dolutegravir) at its health facilities,[7] indicating a more robust and accurate process for forecasting and supply planning for the new treatment regimen. Botswana has one of the highest availability rates among countries that have started the transition to TLD.[8] This improvement in planning and quantification for HIV/AIDS commodities follows training and mentoring support to the MoHW by USAID and the Centers for Disease Control and Prevention (CDC).

1.2 Objective

This report aims to provide health system leaders and policymakers an analysis on the existing global and regional pooled procurement mechanisms to evaluate their benefits for Botswana. It also examines the local procurements modalities to understand specific contextual considerations to guide the GoB to generate recommendations that can inform policy decisions on shaping or adopting pooled procurement mechanism modalities. The report includes key stakeholder reflections on how to contextualize and operationalize pooled procurement. Finally, it proposes some tangible next steps to facilitate informed decision-making on the type of pooled procurement arrangement in which Botswana could engage.

This report does not attempt to provide an in-depth examination of each pooled procurement mechanism or offer detailed guidance on which strategies should be undertaken. It is also not a procurement manual that instructs health system leaders with a stepwise approach to conducting pooled procurement. Rather, the report identifies technical aspects of pooled procurement management and demonstrates how to contextualize and operationalize pooled procurement in Botswana, with regards to legal and capacity needs.

[6] Republic of Botswana February 2018 State of the Nation Address
[7] USAID -Global Health Supply Chain Program "Ensuring ARV Availability at Botswana's Last Mile (February 2020)
[8] Ibid

1.3 Overview of procurement of Essential Medicines and other health supplies in Botswana

Botswana currently has no in-country pharmaceutical manufacturing.[9] Procurement of essential medicines for the public health sector in Botswana is centralized in the MoHW's Central Medical Stores (CMS). With this structure, the designated government entity is responsible for the procurement, warehousing, and distribution of public health medicines and commodities, including ARVs. CMS also forecasts, procures and distributes Botswana's vaccines, pharmaceuticals, and medical devices.[10] However, CMS does not practice strategic procurement but instead uses historical forecasting by reviewing the previous year's vaccine quantities to inform the forecast of the next year.[11] Although efforts are in place to build up a contract management unit, workforce issues, including inadequate numbers and skill mix, leads to weak contract management and administration processes. There are also additional cross-cutting challenges across the health sector related to governance, organizational structures, and workflow optimization, which result in inefficiencies and higher unit costs.[12] As an upper-middle-income country (UMIC), Botswana does not benefit from global arrangements for procuring essential medicines and other commodities that use pooling mechanisms like the Global Alliance for Vaccines and Immunizations (GAVI) and the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM).

In 2018, following training and mentoring support on quantification and forecasting, as well as institutionalization of regular data collection to inform procurement practices, the GoB took over the procurement for previously PEPFAR-funded and -procured HIV ARVs, diagnostic kits, and other essential commodities to generate efficiency gains and avoid stockouts at the CMS in 2019.[13] GoB set ambitious goals for controlling the HIV/AIDS epidemic and ensuring PLHIV have uninterrupted access to their needed treatment.[14] The focus was on new treatment initiations and shifting patients to TLD who had been using tenofovir and emtricitabine (TDF/FTC) and "dolutegravir.[15] The next focus was to shift patients who are using legacy drugs nevirapine, lopinavir/ritonavir, and efavirenz in combination with other ARVs to a TLD regimen. To generate efficiency gains in procurement and avoid stockouts at CMS, GoB took the initial steps to implement strategic procurement and contract practices and is considering pooled procurement mechanisms to ensure uninterrupted medicine and health commodities supply availability in the long term.

[9] Goitseone Montsho 2018 "Healthcare Resource Guide: Botswana."
[10] "Bumpas, Janet. 2008. Study on Comparative Efficiencies in Vaccine Procurement Mechanisms. World Bank, Washington, DC. © World Bank. https://openknowledge.worldbank.org/handle/10986/7963 License: CC BY 3.0 IGO."
[11] Ibid.
[12] Arney, Lesley et al., 2014"Strategic Contracting Practices to Improve Procurement of Health Commodities."
[13] USAID Global Health Supply Chain 2020 "Supplying Health Professionals with Procurement and Contract Management Skills | USAID Global Health Supply Chain Program."
[14] Ibid
[15] Ibid

The purchasing approaches of central-level management result in multiple agencies involved in parallel processes. Within MoHW, HIV response-related functions are managed at nine different functional areas that are also involved in procurement and supply chain management. The actual number of units and divisions is even higher when considering the entire health system. These procurement entities also have challenges in planning and forecasting; using efficient procurement methods; and often tender yearly or multiple times a year resulting in increased commodity costs, tender delays, long lead times, and stockouts. "Another inefficiency relates to central-level management, where there may be many agencies involved in parallel processes. The Supply Chain Management Systems (SCMS) project lists nine agencies within the MOH that are involved in procurement and supply chain management as part of the HIV response."[16] The actual number of agencies is likely higher when considering the entire health system. A regional document notes that this problem is common throughout Southern African states and can "stretch the already overwhelmed public sector medicines supply systems" (South African Development Community Secretariat 2007). The United Nations Programme on HIV and AIDS (UNAIDS) also notes there is a greater need for integration of procurement mechanisms across vertical programs (UNAIDS 2015).

1.4 Defining key concepts for the study

An effective health procurement system seeks to have the right medicines of recognized quality available in the right quantities and at reasonable prices.[17] Effective procurement management is the process of "managing the buyer-seller relationship that ensures transparent and ethical transactions so that the buyer receives the correct goods, and the seller receives timely payment."[18] The main procurement methods used by health systems are open tender, restricted tender, competitive negotiation, or direct negotiation.[19]

- *Open Tendering* aims to acquire goods and/or services at the lowest price. There is a belief that open tendering stimulates competition and minimizes discrimination. It's also known as open competitive bidding, open competition, or open solicitation.
- *Restricted Tendering* limits the request for tenders to a select number of suppliers, contractors or service providers. This method of procurement is also called Limited Bidding and Selective Tendering.
- *Competitive Negotiation* negotiates the pricing and terms surrounding a particular transaction. This method is based around the concept that negotiations are a zero-sum game; meaning that one party must win the negotiation while the other party loses. This concept is in direct contrast to cooperative negotiation methods, which conclude that there can be multiple winners in a negotiation, resulting in a win-win scenario for all the involved parties.
- *Direct Negotiation* is a procurement method where there is no competitive process and negotiations are entered into with one or more vendor.

[16] (SCMS 2012)" SCMS. 2012. In Botswana, transforming supply chains, transforming lives- In SCMS in Brief
[17] Management Sciences for Health, (2012) MDS-3: Managing Access to Medicines and Other Health Technologies.
[18] ibid
[19] ibid.

Purchasing can occur at different levels of the health system and evidence shows that centralized procurement results in cost savings and improved quality.[20] Additional evidence demonstrates that procurement systems at the country level are often unable to get the lowest prices for commodities since this requires generating larger orders while maintaining responsiveness to the changing demands of health facilities.[21] Several countries have opted to collaborate on pooled procurement to achieve better unit costs for essential medicines at current consumption volumes.[22]

1.5 Overview of pooled procurement

Pooled Procurement, also known as joint purchasing, is a form of cooperation where several buyers aggregate their purchases to increase their bargaining power and influence on the market.[23] The buyers could be organizations within a single country or health agencies across countries. The buyers' alliance acts as a single unit, a monopsony, incentivizing competition among suppliers.[24] Globally, pooled procurement of pharmaceuticals and vaccines has gained prominence as an efficient strategy to address challenges that hinder the accessibility of essential medicines.[25] It is important to note that there is limited evidence showing that centralizing procurement reduces stockouts or increases the availability of health products.[26] Nevertheless, there are several global and regional initiatives for pooled procurement and several ways to aggregate demand. This ranges from less formal agreements on information exchange (for example, on product prices, quality, and suppliers) to formalized governance structures where entities or countries negotiate, contract, and purchase together.

Pooled procurement has several advantages that countries can leverage. The mechanism creates economies of scale, leading to reduced pharmaceutical product unit prices, result in increased access to essential medicines.[27] Moreover, there may be reduced transaction costs and administrative burdens on individual countries due to the joint standardized purchasing process. Pooled procurement may reduce inefficiencies and corruption in the procurement process as the mechanism engages fewer suppliers who meet pre-qualification criteria. It also facilitates harmonizing standard treatment guidelines, medicine registrations, and essential medicines lists among participating countries.[28] This harmonization of standards leads to improved quality assurance and reduces sub-standard products in the participating countries, especially if they

[20] Millington and Bhardwaj, (2017) "Evidence and Experience of Procurement in Health Sector Decentralization."
[21] Management Sciences for Health, 2012 *MDS-3: Managing Access to Medicines and Other Health Technologies*
[22] Huff-Rousselle, 2012"The Logical Underpinnings and Benefits of Pooled Pharmaceutical Procurement: A Pragmatic Role for Our Public Institutions?"
[23] Maggie Huff-Rousselle. –1996 Cost Containment Through Pharmaceutical Procurement: A Caribbean
[24] ibid
[25] Organisation of Islamic Cooperation, 2010 "Draft Concept on Pooling of Procurement of Pharmaceuticals and Vaccines."
[26] Seidman G.and Atun, 2017"Do Changes to Supply Chains and Procurement Processes Yield Cost Savings and Improve Availability of Pharmaceuticals, Vaccines or Health Products? A Systematic Review of Evidence from Low-Income and Middle-Income Countries."
[27] World Health Organisation, 2019"Nine African Countries Agree to Begin Journey towards Pooled Procurement to Increase Their Access to Affordable Life-Saving Vaccines."
[28] Abdallah, H 2005"West Africa Reproductive Health Commodity Security. 'Review of Pooled Procurement.'"

share geographical boundaries.[29] A key lesson from long-running pooled procurement mechanisms is that the volumes represented by the mechanism are not what leads to price reduction, but the effect of a powerful single buyer that acts as a lever to change competitive behavior among suppliers, making them offer better prices and engage in more transparent transactions.[30] Therefore, as countries seek to enter pooled procurement arrangements, they need to be willing to make a sustained commitment to the mechanism (monopsony commitment)[31] for it to be effective.

1.5.1 Country characteristics for pooled procurement

According to the World Health Organization (WHO), pooling arrangements for essential health commodities can be beneficial to countries that have at least one of the following characteristics:

- *Geographic isolation or a small population.* This includes island states and countries with small populations that may have limited capacity to directly procure commodities, conduct quality assurance checks, and secure timely supply. Pooling mechanisms enable them to combine orders and improve their negotiation with suppliers.[32]
- *Existing regional or inter-country body*. Some countries already have regional or group initiatives with structures that they can leverage to conduct their procurement, quality assurance and financing.
- *Limited negotiating capacity*. Countries that experience difficulties with any of the key components of procurement relative to neighboring or similar countries.
- *Internal difficulty establishing demand*. Countries that find it challenging to quantify needs for future implementation of new vaccines or that have trouble mobilizing resources, conducting negotiations, coordinating processes with large multinational companies, or justifying the potential of new vaccines to national decision-makers.

Botswana has a population of approximately 2.2 million people; this relatively small population makes Botswana vulnerable to high prices for the small volumes it would need to purchase independently. Similarly, without strong local regulation, countries like Botswana may have inadequate quality assurance compared to the global standards imposed by donors, thus threatening the quality of its drug supply.[33] Insufficient quality control is listed among the top causes of inefficiencies related to health systems.[34]

[29] SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study.
[30] Huff-Rousselle, 2012"The Logical Underpinnings and Benefits of Pooled Pharmaceutical Procurement: A Pragmatic Role for Our Public Institutions?"
[31] Maggie Huff-Rousselle. (1996) Cost Containment Through Pharmaceutical Procurement: A Caribbean
[32] World Health Organisation, (2019) "Nine African Countries Agree to Begin Journey towards Pooled Procurement to Increase Their Access to Affordable Life-Saving Vaccines."
[33] Maggie Huff-Rousselle. –(1996) Cost Containment Through Pharmaceutical Procurement: A Caribbean
[34] Chisholm, D., and D. Evans. 2010. Improving health system efficiency as a means of moving towards universal coverage. In World Health Report (2010) background paper

2 Methodology

2.1 Study design

A qualitative cross-sectional study design was used to analyse procurement entities and related functionaries, including supply chain management, and sought to answer the research question: *What can Botswana learn from existing global and regional pooled procurement mechanisms to better evaluate the benefits of pooled procurement?* This qualitative study was conducted in two phases.

i. *Phase 1: Desk review*

The desk review used a 2-step-approach. First, the review focused on successfully implemented global and regional pooled procurement mechanisms for medicines and other health supplies in other African countries to draw lessons for Botswana. Second, the review focused on country examples in the region for Botswana to consider when building up its capacity for pooled procurement of essential medicines and other commodities. A scoring criterion was developed to rank eight UMIC African countries to ensure comparability to Botswana. The criteria included: *per capita GDP; population size; current total health expenditure; domestic general government health expenditure per capita; out-of-pocket expenditure; incidence of malaria; incidence of tuberculosis (TB); ARV therapy coverage; share of adults (ages 15+) living with HIV; and proximity to Botswana.* Indicators were scored on a three point system – three points were awarded to the country most like Botswana (ex: Gabon for "per capita GDP"), two points to the second, and one point to the third closest indicator values (ex: Libya and South Africa for "per capita GDP"). The top four highest scoring countries were selected - South Africa, Namibia, Gabon, and Algeria (See Appendix 1). Additionally, the research team included Rwanda and Tanzania due to their experience with pooled procurement.

ii. Phase 2: Primary interviews

Based on the desk reviews' secondary data sources, the second phase used semi-structured and recorded key informant interviews to gain insights on potential local pooled procurement and understand Botswana specific contextual considerations. Key informants were selected based on their expertise in procuring medicines and medical supplies representing government agencies (Botswana MoHW; Medicines Regulatory Authority, public procurement management board, and the National AIDS and Health Promotion Agency [NAHPA]), the private sector (medical products procurement; distribution entity) and development partners (USAID, GHSC-PSM, Regional Economic Community[35] and some UN Agencies. Key informants were also requested to recommend other potential experts to interview. This snowball sampling method allowed the research team to increase the total number of interviewees and reach experts who would have otherwise been non-accessible. Due to the current global pandemic and travel restrictions, interviews were conducted virtually (Skype, Zoom, Microsoft Teams, and telephone).

[35] Regional Economic Communities are regional groupings of African States and are the pillars of the African Union. They facilitate regional economic integration between members of the individual African regions. Currently, they are eight communities.

The research team triangulated key informant interview findings with the desk review to obtain a broader picture of the research question. Researchers then adopted an inductive approach to identify the key themes emerging from the interviews and then the study team used NVivo (a qualitative data analysis software) to analyse the data. This thematic approach allowed in-depth contextual analysis to understand common patterns, identify underlying themes, and draw out emerging insights. As the stakeholder insights provided were on diverse aspects of pooled procurement, the research team used the Strengths/Weaknesses/Opportunities/Threats (SWOT) analysis as a framework to cluster common themes. The SWOT analysis provides an enhanced understanding of how different factors interplay in the decision to increase the use of pooled procurement. Given that the SWOT analysis is a tool to support strategic decision making, the results will support a systematic reflection on the current internal competencies and external factors to manage for Botswana to benefit from pooled procurement mechanisms.

2.2 Analysis framework - WHO models of pooled procurement

The WHO's models of pooled procurement framework[36] were used to analyze and categorize various pooled procurement mechanisms. The framework has four levels which form a continuum of increasing cooperation in the procurement process. Levels one and two focus on information sharing between participating countries, while levels three and four entail joint purchasing.[37] Pooled procurement is a process, and countries need to build the required frameworks to enable sustained collaboration on joint purchasing.[38] Each level can be a standalone mechanism, or based on the strategy of the collaborating bloc, be a step to move to greater levels of collaboration.[39] Therefore, the conceptual framework is used to understand the different levels and forms of collaboration that occur between countries to facilitate greater buyer power.[40]

Table 1: Four levels of pooled procurement

Level	Collaboration Mechanism	Description
Level 1	Informed buying	Also defined as information sharing. Member countries share information, particularly about suppliers, products, and prices. Procurement is conducted individually.

[36] World Health Organisation, 2017 "WHO | Procurement Mechanisms and Systems."
[37] Management Sciences for Health, 2012 *MDS-3: Managing Access to Medicines and Other Health Technologies*.
[38] World Health Organisation, "Joint Bulk Purchasing of Essential Drugs - Achats Groupés de Médicaments Essentiels (A.C.A.M.E. - WHO/AFRO, 1999, 28 p.): PART I - *study visit to the secretariats of essential drugs joint bulk purchasing systems in countries of the Maghreb and the Gulf."*
[39] World Health Organisation, 2017 "WHO | Procurement Mechanisms and Systems."
[40] Huff-Rousselle, 2012 "The Logical Underpinnings and Benefits of Pooled Pharmaceutical Procurement: A Pragmatic Role for Our Public Institutions?"

Level 2	Coordinated informed buying	Also defined as coordinated information sharing. Member countries undertake joint market research, share supplier performance information, and monitor prices. Procurement is conducted individually.
Level 3	Group contracting	Member countries jointly negotiate prices, select suppliers, and agree to purchase from the selected suppliers using group contracts. Procurement is conducted individually by the countries.
Level 4	Central contracting and procurement	Member countries jointly conduct tenders and award contracts through an organization acting on their behalf. The central procurement unit pools the financial resources from the member countries and manages purchases on their behalf. (*Note: All elements of the previous three stages of pooled procurement should be adopted before embarking on a centralized contracting model.)
	Group purchasing and distribution	Centralized distribution organization combining group purchasing and supply chain.

2.3 Study limitations

The stakeholder reflections study report has a few limitations. Because it relies on the experiences and opinions of a limited number of experts identified as knowledgeable about pooled procurement in Botswana, the results could have been different had other informants been interviewed. Also, several invited informants who would have provided additional information and context could not participate in the interviews. The limited number of interviews might create deficiencies in data interpretation as the study might not have uncovered all the intricacies of the pooled procurement situation in Botswana. Therefore, the results should be interpreted in combination with other information available regarding the procurement function in Botswana.

3 Findings

This section reviews and presents findings on both regional[41] and global[42] pooled procurement mechanisms to draw key lessons for Botswana's health system. Each reviewed procurement mechanism was categorized into a level and highlighted successes and challenges to draw opportunities that Botswana could benefit from.

3.1 Regional pooled procurement mechanisms

Several regional arrangements for pooled procurement have been established and trialed across

[41] Regional Pooled Procurement mechanisms included: Southern African Development Community, East African Community, Pan American Health Organization, Association Africaine des Centrales d'Achats de Médicaments Essentiels.

[42] Global Pooled Procurement mechanisms included: GFATM, WHO Global Drug Facility, UNICEF, and GAVI

Africa over the last two decades. Additionally, the Pan American Health Organization (PAHO) mechanism was also included due to its distinction as one of the longest-running pooled procurement mechanisms. The experiences from each of these joint purchasing arrangements would be important for Botswana as it considers engaging in pooled procurement. Of the regional mechanisms highlighted below, Botswana would only be eligible to participate in the SADC pooled procurement mechanism.

Table 2: Summary of regional pooled purchasing mechanisms

Note: All the data presented in this table are expounded in the cases in the next page.

Details	**SADC**	**EAC**	**ACAME**	**PAHO***	**ECDS**	**GCC**
Established	2012	2000	1996	1977	1986	1976
Region	Southern Africa	Eastern Africa	Central and West Africa	North, Central & South America & the Caribbean	Eastern Caribbean	Gulf States
No. of member countries	16	6	22	35 (serves 41 countries)	10	6
Intended procurement model	Group contracting	Group contracting	Central contracting	Central contracting	Group contracting	Group contracting
Current Model	Informed buying	N/A	N/A	Central contracting	Central contracting	Central contracting
Comments		*Regulatory harmonization*	*Central contracting pilot in 1998*	*2-pooled mechanisms: Revolving Fund and Strategic Fund*	*[43]Weakening due to late payment by members*	

SADC - Southern African Development Community; EAC - East African Community; ACAME - Association Africaine des Centrales d'Achats de Médicaments Essentiels; PAHO - Pan American Health Organization; ECDS – Eastern Caribbean Drug Service; GCC – Gulf Cooperation Council's Group Purchasing Programme

**Explanatory note:* While PAHO is managed by the WHO, it has been classified as a regional mechanism because it exclusively serves countries in a specific region. Its operations and learnings are therefore comparable to other regional pooled procurement mechanisms.

[43] Huff-Rousselle, 2012 "The Logical Underpinnings and Benefits of Pooled Pharmaceutical Procurement: A Pragmatic Role for Our Public Institutions?"

3.1.1 Southern African Development Community (SADC)

The SADC region bears a disproportionate burden of HIV, TB, and malaria diseases and has a growing incidence of non-communicable diseases such as heart disease, diabetes, and cancer.[44] In 2012, SADC adopted a Strategy for Pooled Procurement of Essential Medicines and Health Commodities to ensure access to affordable, safe, effective, quality-assured products and increase market efficiencies. The strategy recommends a group contracting model delivered incrementally through a staged approach that starts with coordinated information exchange and work sharing. This approach is expected to result in financial savings.[45] The stages of the group contracting model include:[46]

- *Stage 1*: Coordinating information sharing on medicine quality and price
- *Stage 2*: Developing and implementing good practices
- *Stage 3*: Coordinated work-sharing through the exchange of existing "good practices" among the Member States
- *Stage 4*: Establishing the coordination agency: SADC Pharmaceutical Procurement Services
- *Stage 5*: Regional tendering for prequalification of regional suppliers and products
- *Stage 6*: Regional framework contracts with suppliers under which the Member States purchase directly from suppliers (group contracting)

> *"Successful procurement depends on technical capacity, financial resources, good information systems, efficient management and availability of suppliers. Effective policies, legislation, regulations, and guidelines underpin the processes. Strong political will and economic commitment are needed to support pooled procurement."*
> ***– SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities (2013-2017)***

This strategy is intended to enable all SADC Member States to reach minimum standards of acceptable procurement and supply management (PSM) systems while allowing those member states that have attained higher PSM standards to advance more rapidly towards adopting group contracting.[47] The SADC strategy states that pooled procurement will be made through the SADC Pooled Procurement Services (SPPS) who will procure medicines and other medical equipment on behalf of the 16 other member states of SADC.[48] Through this system, SADC members can trade with big pharmaceutical manufacturers who do not usually sell medicines to individual countries. This pharmaceutical pooled procurement mechanism allows member states to share pricing and supplier information to enable negotiations for better prices for high quality medicines from suppliers, thereby significantly reducing the administrative cost of procurement.

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[44] 'Hellen t Hoen, Kujinga, and Boulet 2018, Journal of Pharmaceutical Policy "Patent Challenges in the Procurement and Supply of Generic New Essential Medicines and Lessons from HIV in the Southern African Development Community (SADC) Region."
[45] SADC, "Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017."
[46] ibid
[47] SADC. ,2018 "SADC, Tanzania Discuss SADC Pooled Procurement of Pharmaceuticals Services."
[48] SADC,2018 "SADC, Tanzania Discuss SADC Pooled Procurement of Pharmaceuticals Services."

As of September 2018, MSD had signed contracts with a total of 122 manufacturers of pharmaceutical and medical supplies[49]. As a result, MSD was also able to reduce the price of the medicines by 15-80 percent, depending on the medicine type, with a general average of 40 percent for purchases that would be made by member states through pooled procurement.[50] Additionally, the Southern African Programme on Access to Medicines and Diagnostics (SAPAM), under SADC's pooled procurement activities, reported there being a functional pooled procurement network (PPN) that supports information sharing among the member states.[51]

Despite SADC's process, it continues to face several significant future challenges to pooled procurement, to reach the goal of a harmonised regional economic bloc. Pooled procurement is not just a technical exercise; it has political and economic dimensions that cannot be ignored. The member states of the SADC are characterized by the significant economic imbalances that exist among them. Those imbalances further hinder the members' ability to integrate their economies and help create a situation in which the stronger economies, such as South Africa, effectively hold a balance of power and often can dictate terms when negotiating with smaller counterparts more effectively. South Africa accounts for over 60 percent of all intra-SADC trade, as well as 70 percent of the total SADC gross domestic product.[52] Given that South Africa possesses such a comparatively stronger economy than the other SADC members, it also holds less commitment to regional integration, because it has a commensurately greater ability to attract interest from other trading partners across the globe.[53] If the SADC is to prove its legitimacy as a genuinely effective regional organization for pooled procurement, it will have to find workable solutions to the potentially problematic political and economic concerns that are at play among member countries. This will entail SADC ensuring that all member states are actively involved in the process of adopting and implementing pooled procurement and take ownership of the regional pooled procurement programme. Further, a contractual and binding agreement should be signed among the SADC member states specifically for the implementation of pooled procurement to strengthen the organizational commitment.

Another challenge to the creation of a regional pooled procurement mechanism is the overlapping membership of SADC member states in other intergovernmental networks. This remains a bottleneck to the development of a homogenous procurement legislative environment, which provide the basis for good pharmaceutical procurement practices for regional pooled procurement. For instance, Namibia and Swaziland are both members of the Southern African Customs Union (SACU), as well as the Common Market for Eastern and Southern Africa (COMESA), and both participate in the Regional Integration Facilitation Forum (RIFF). Most SADC states are also COMESA members. Overlapping membership can be costly, as governments must negotiate in several different forums, possibly agreeing to the implementation of potentially conflicting policies. The simultaneous membership of more than one regional

[49] Ibid
[50] https://dailynews.co.tz/news/2018-12-275c24764431d53.aspx
[51] Southern African Program on Access to Medicines and Diagnostics 2017 SAPAM Projects.
[52] Wilson Bell (2017) The Southern African Development Community: Solid Achievements and Future Challenges
[53] Ibid

economic cooperation can also force states to accept measures that may not necessarily be in their best interests. A pertinent example is that cited by Mapuva and Muyengwa-Mapuva[54] of the SACU, to which South Africa, Namibia, Botswana, Lesotho and Swaziland are members. South Africa has already negotiated a Trade and Development Co-operation Agreement with the European Union (EU), as well as with the SACU. Hence, the terms of any agreements concluded must also include the other SACU members. If the SADC-EAC-COMESA Tripartite Free Trade Area (TFTA) is successfully established, it would help overcome the challenges posed by overlapping memberships, as it aims to create a free trade agreement between all the SADC, COMESA and East African Community (EAC) member states. This will further enable SADC to address the capacity of local production concerns to meet the selection of needed medicines, pooled quantities, good manufacturing practices, quality of products, and WHO pre-qualification scheme requirements, especially where donor funding is involved. This will also improve the quality and the pooling of local capacity to meet regional needs that will benefit not only the specific countries that produce medicines but the entire region as an economic bloc. However, the TFTA agreement is unable to influence issues concerning outside organisations, such as the EU. Although all SACU member countries are also members of the SADC, the EU has negotiated with them separately. The SACU was able to organise economic partnership agreements with the EU without reference to the SADC, creating a divide within the SADC member states.[55]

Moreover, within the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), there are legal options that allow low-income countries to access generic medicines at lower costs.[56] These legal options, termed TRIPS flexibilities, have previously been used by individual SADC countries to enable procurement of lower-priced generics. As half of the SADC countries are classified as Least Developed Countries, the bloc can utilize the regional exception which would allow all countries in the region to access lower-priced generics.[57] The fact that pooled procurement has been on the SADC agenda for more than 10 years reflects strong commitment, both at policy and executive level. However, commitment to pooled procurement of medicines should be sufficiently reflected in the National Health Policies and National Medicines Policies of member states.

3.1.2 East African Community (EAC)

Pooled procurement has been on EAC's agenda since the early 2000s and resulted in the approval of the "Regional Group-Contracting Bulk Procurement Model" during the 15th session of the EAC Council of Ministers in 2008. However, this initiative did not translate into the actual implementation of a pooled procurement mechanism and has made limited progress since then.[58]

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[54] Mapuva, J. and Muyenga-Mapuva, L., 'The SADC Regional Bloc: What Challenges and Prospects for Regional Integration?', Law, Democracy and Development, University of the Western Cape, Vol. 18, 2014, para. 4

[55] Wilson Bell (2017) The Southern African Development Community: Solid Achievements and Future Challenges

[56] Helen 't Hoen, Kujinga, and Boulet, 2018 *Journal of Pharmaceutical Policy* "Patent Challenges in the Procurement and Supply of Generic New Essential Medicines and Lessons from HIV in the Southern African Development Community (SADC) Region."

[57]. Ibid

[58] Syam, Nirmalya. "Regional Pooled Procurement of Medicines in the East African Community," September 2014, 56

In contrast, EAC has been active in harmonizing and improving the policy and regulatory environment for procurement among its member states. Through the African Medicines Regulatory Harmonization (AMRH) Initiative, EAC has taken strides towards better coordination and harmonization to improve its autonomy, including pharmaceutical product procurement. The AMRH led to greater integration and harmonization resulting in reduced drug approval time and increased joint registration. Moreover, the 2019 legal common market protocol now allows regional pharmaceutical producers to be treated as "local," thus favoring the development of the regional industry. Steps have also been taken to assess local manufacturers' compliance with good manufacturing practices, including supporting local companies to meet the standard.[59]

3.1.3 African Association of Central Medical Stores (ACAME)

ACAME, established in 1996, stems from 22 francophone Central and West African countries interest in pooled procurement of essential medicines. To date, ACAME records only one successful pooled procurement - the joint purchase of 5 antimicrobials in 1998 by Guinea, Mali, and Niger.[60] Since then, ACAME serves to promote cooperation and harmonization of pharmaceutical policies and regulations amongst member countries.[61] In 2008, ACAME signed a Memorandum of Understanding with Union Economique et Monetaire Ouest-Africaine (UEMOA) to act as the procurement mechanism for the regional bloc.[62] In its 2017-2021 strategic plan,[63] ACAME listed objectives to improve the performance of member states' central medical stores and increasing information sharing among them. Some metrics identified were ensuring sustainable availability of quality health products at competitive prices and that all central medical stores use an integrated information management system. ACAME's 2017-2021 strategic plan identified challenges to its role as an information-sharing platform and capacity building partner for country medical stores including the increased market share of international organizations in the pharmaceutical products market to the detriment of central medical stores, the privatization of the distribution of medicines, and insufficient provision of health budgets.

3.1.4 Pan American Health Organization (PAHO)

PAHO's Revolving Fund, established in 1978, is one of the most successful vaccines pooled procurement mechanisms. Its success may be attributed to the fact that member countries waived some of their regulations (such as the requirement for market authorization) as confidence grew that the PAHO mechanism could guarantee the best prices for quality vaccines.[64] It procures vaccines for 41 countries and territories in Latin American and the

[59]Nemzoff, C., Kalipso Chalkidou, and Mead Over. "Aggregating Demand for Pharmaceuticals Is Appealing, but Pooling Is Not a Panacea," May 2019. https://BoMRA.cgdev.org/publication/aggregating-demand-pharmaceuticals-appealing-pooling-not-panacea.

[60] World Health Organization, 2014 "Regional Workshop on Strengthening Quantification and Procurement of Essential Medicines: Report of a Regional Workshop."

[61] ibid

[62] The Association of Central African Purchases of Essential Medicines, "ACAME 2008- Historical.Memorandum of Understanding Union Economique et Monetaire Ouest-Africaine (UEMOA) "

[63] Sonde, Issaka, "Plan stratégique 2017-2021 de l'ACAME."

[64] SADC 2012 Report: Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study

Caribbean using funds primarily provided by national budgets. Member countries transfer funds to PAHO Revolving Fund, who orders in bulk, benefiting from low prices due to the large procurement pool. PAHO also has a Strategic Fund established in 2000 that runs similarly as the Revolving Fund and supports joint procurement of medicines and diagnostic kits for vector-borne diseases.[65] PAHO uses annual contracts because most member countries budget annually and cannot use multi-year contracts. It operates a central contracting model that can negotiate low vaccine prices due to the aggregated demand from several member countries.

3.1.5 Eastern Caribbean Drug Service (ECDS)

The ECDS, established in 1986, with ten members[66] representing about 1 million people. The mechanism aims to "maximize healthcare services of the Organization of Eastern Caribbean States (OECS) countries by pooled procurement and management of pharmaceuticals and related medical supplies."[67] It is self-financing through a 9 percent surcharge to member states and allows restricted international bids for 550 medicines (840 health products)[68] from 30 suppliers. ECDS follows a central contracting and procurement approach where countries identify medicines based on their needs and submit the requisition to the ECDS Pharmaceutical Procurement Service (PPS), who orders from suppliers. Payments are made by the Eastern Caribbean Central Bank (ECCB) once suppliers have delivered the products to the member countries.

In addition to pooled procurement, the ECDS promotes adopting best practices through conferences and workshops. Through the PPS, it conducts the monitoring of purchased pharmaceuticals' delivery and quality to ensure that ECDS quality standards are met.[69] The use of the PPS led to significant efficiency gains, with costs cut by 20 percent through economies of scale, corresponding to annual cost savings amounting to USD 4 million.[70]

3.1.6 Gulf Cooperation Council Group Purchasing Program

The Gulf Cooperation Council's (GCC) Group Purchasing Programme (Gulf Joint Procurement Program) was launched in 1976. It serves six Gulf States' ministries of health and twelve public hospitals in Saudi Arabia; its permanent secretariat is Saudi Arabia. As a small market, the GCC procures exclusively from high-cost American and European producers due to member states' demands.[71] The countries served by the program have harmonized their drug formularies and

[65] Nemzoff, C., Kalipso Chalkidou, and Mead Over. "Aggregating Demand for Pharmaceuticals Is Appealing, but Pooling Is Not a Panacea," May 2019. https://BoMRA.cgdev.org/publication/aggregating-demand-pharmaceuticals-appealing-pooling-not-panacea.

[66] Burnett, Francis,2017"Organisation of Eastern Caribbean States (OECS) Pharmacetucial Procurement Service (PPS)."

[67] ibid

[68] World Health Organization, 2014 "Regional Workshop on Strengthening Quantification and Procurement of Essential Medicines: Report of a Regional Workshop."

[69] Burnett, Francis, (2017) "Organisation of Eastern Caribbean States (OECS) Pharmaceutical Procurement Service (PPS)."

[70] ibid

[71] Matsoso, Precious, Velasquez, German, Forte, Gilles, and Quick, Jonathan. "Using Indicators to Measure Country Pharmaceutical Situations," 2006. https://BoMRA.who.int/medicines/publications/WHOTCM2006.2A.pdf.

standardized the related product specifications to have a single formulary for the region.[72] All prequalified suppliers must have an agent or a local partner in Saudi Arabia to participate in the tendering process for the GCC. Tender documents sold at USD 1,300–4,000 through the local representative to the supplier. If all suppliers return with high bids compared to the prior year, another round of bidding occurs. Like the PAHO Revolving Fund, accepted tenders set the price but does not require the purchase of specified volumes; the binding agreement occurs when countries and suppliers contract directly.[73] One of the reasons cited for the success of the mechanism is that member countries have committed to using this central contracting mechanism for at least 60 percent of their public health commodities.[74] Additionally, the participating countries share a common culture, and they all have high performing economies.[75]

[72] "WHO South-East Asia | World Health Organization." Accessed October 26, 2020. https://BoMRA.who.int/southeastasia.

[73] DeRoeck, Denise, Saleh A. Bawazir, Peter Carrasco, Miloud Kaddar, Alan Brooks, John Fitzsimmons, and Jon Andrus. "Regional Group Purchasing of Vaccines: Review of the Pan American Health Organization EPI Revolving Fund and the Gulf Cooperation Council Group Purchasing Program." *The International Journal of Health Planning and Management* 21, no. 1 (March 2006): 23–43. https://doi.org/10.1002/hpm.82

[74] World Health Organization, 2014 "Regional Workshop on Strengthening Quantification and Procurement of Essential Medicines: Report of a Regional Workshop."

[75] ibid

3.2 Enabling factors and challenges

Table 3: Synthesis of enabling factors and challenges across regional pooled procurement mechanisms

Details	Factors	SADC	EAC	ACAME	PAHO*	ECDS	GCC
Enablers	Institutional home for mechanism				√	√	√
	Level of pooled procurement (Central contracting versus other types)				√	√	√
	Mechanism provides capacity building to members to support joint procurement		√				√
	Ownership by national governments - stipulated financial contribution					√	√
	Purchases are based on needs of all participating countries				√	√	√
	Homogeneity - Members have similar economic and cultural context					√	√
	Built-in incentives to suppliers (such as minimum order quantities)					√	√
Bottlenecks	Lack of harmonized medicines regulation policies	√	√	√			
	Limited resources allocated to joint purchasing by members	√		√	√		
	Difference in economic status of member states	√		√	√		
	Lack of an institutional home for mechanism			√			
	Competition from global pooled procurement mechanisms			√			

3.3 Global pooled procurement mechanisms

Traditionally, United Nations agencies have used pooled procurement to obtain commodities for their country programs.[76] Increased funding for procurement and a trend of ear-marking development assistance to specific disease areas have led to establishing additional global procurement facilities.[77] Given the relatively large number of global procurement mechanisms, this report focuses on those relevant to TB, sexual and reproductive health, HIV/AIDS and child health. Table 4 highlights global pooled procurement arrangements run by GFATM , GAVI the Vaccine Alliance, WHO Global Drug Facility (GDF), the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA) and the Clinton Health Access Initiative (CHAI).

Table 4: Summary of global procurement mechanisms

Details	GFATM	UNICEF	GAVI	WHO	UNFPA	CHAI*
Focus Commodities	HIV/AIDS, TB, and malaria related medicines	Vaccines	Vaccines	TB medicines	Reproductive health commodities	2nd line antiretrovirals
Eligibility Criteria	Income classification[78] Disease burden of HIV, TB, and malaria	Countries that have donor support OR Countries that can pay in advance using national funds	GAVI Eligibility and Transition policy	Grants to low-income countries OR Direct procurement for countries with adequate finances	Donor programs International NGOs Third-party country clients[79]	Countries seeking to introduce second line ARVs
Alternatives for non-eligible/ transitioning countries	May be eligible for 1 component	N/A	UNICEF pooled procurement with administrative fee	GFATM	N/A	N/A
Botswana eligibility	TB	Yes, on condition of pre-payment	No	TB Medicines	Yes – self funded	Yes

[76] Management Sciences for Health, 2012 *MDS-3: Managing Access to Medicines and Other Health Technologies*.

[77] Huff-Rousselle, Maggie. "The Logical Underpinnings and Benefits of Pooled Pharmaceutical Procurement: A Pragmatic Role for Our Public Institutions?" *Social Science & Medicine (1982)* 75 (July 11, 2012): 1572–80. https://doi.org/10.1016/j.socscimed.2012.05.044.

[78] All low and lower-middle income countries are eligible, regardless of disease burden. Upper-middle income countries must have at least a 'high' burden of disease to be eligible for Global Fund financing.

[79] These are in country clients who receive UNFPA procured supplies at the request and on behalf of third parties (Governments, United Nations Specialized Agencies, intergovernmental organizations, non-governmental organizations, or Nation's entities, including funds, programmes, and subsidiary organs of the United Nations)

Comments		*Requires pre-payment* *Administrative fee for self-financed*	*Administrative fee for non-eligible countries*	Botswana is self-funding	*Requires pre-payment* *No country representation in tender committee*	*High set up cost for mechanism*

* *Explanatory note:* CHAI pooled procurement mechanism was a time-bound modality because it was undertaken as part of a donor-funded project, unlike the other global mechanisms described. It was highlighted due to the lessons for transitioning countries and because Botswana was one of the participating countries.

3.4 Insight from global and regional procurement mechanisms

As more countries face multiple donor funding transitions, disease profiles, and demographic structures,[80] mechanisms such as pooled procurement that increase the efficiency of resources within the health sector will become increasingly important. Based on this review of global and regional pooled procurement mechanisms as well as the experiences of countries highlighted in the case studies (Annex 3), the following key takeaways emerge:

- *Pooled procurement is a process.* Conceptual frameworks, such as the WHO Levels of Pooled Procurement framework, that describe pooled procurement illustrate it as distinct mechanisms. However, in practice, countries need to approach pooled procurement as a continuum and understand that progress may be iterative. For example, using the regional mechanisms reviewed in this report, most of them set out to achieve either group contracting (level 3) or central contracting (level 4). However, once implementation started, most faced constraints that forced them to work at the level of information sharing (level 1) while establishing structures to support the improvement of procurement systems in individual member states and harmonizing policies needed for joint purchasing. From a country perspective, it is important to understand that even seemingly lower levels of collaboration that only involve information sharing are beneficial. In addition to allowing harmonization of policies and processes, information sharing builds the foundation of trust required to pool funding across countries.

- *Pooled procurement requires an enabling environment.* Based on the experiences of the countries highlighted, when a country decides to participate in regional pooled procurement mechanisms, it is important to be aware that this will necessitate policy and regulatory re-alignments to enable a harmonized regulatory approach to medicines and pharmaceutical supplies that enhances information sharing and better-quality standards. Additionally, countries may be required to set up new structures, such as an autonomous medicines regulatory authority to participate effectively in pooled procurement with peers. The evolution of the regional pooled mechanisms illustrates how a few countries falling behind

[80] Yamey, GAVIn, Osondu Ogbuoji, and Justice Nonvignon. "Middle-Income Countries Graduating from Health Aid: Transforming Daunting Challenges into Smooth Transitions." *PLOS Medicine* 16, no. 6 (June 25, 2019): e1002837. https://doi.org/10.1371/journal.pmed.1002837

can lead to a non-functional mechanism. Therefore, countries need to undertake the necessary internal sensitization with key decision makers to facilitate the reforms.

- *Regional pooled procurement mechanisms require a sustained commitment from member states.* One of the foundational premises for pooled procurement is that it creates a new market dynamic (monopsony) where power shifts to the buyer through demand aggregation. To reap the benefits of the changing market dynamics, countries cannot engage in pooled procurement mechanisms as a one-off. This is because evidence has shown that the benefits of pooled procurement mechanisms have the power to influence and change the behavior of suppliers by creating sustained incentives for them to lower prices in exchange for better payment terms and consistent repeat orders. While it may be beneficial or convenient for a country to only engage in regional pooled mechanisms on an as-needed basis, this weakens the negotiation power of the buying unit. The implication of this is that pooled mechanisms need binding agreements that countries sign up to and enforce to create a sustained monopsony.

- *The administrative structures of global and regional mechanisms may influence their success*. The examples in this report demonstrate a distinct difference in global and regional pooled procurement setup. Regional and global ownership differ as participating member states are regional mechanism owners that often start as a regional bloc made up of diverse member states, while global is owned and run out of a single organization. This difference is crucial to how the mechanism is administered. While a global organization has the structures to second staff to run a pooled mechanism, regional pooled mechanisms must figure out how to set up a secretariat and fund it. The result is that regional pooled mechanisms in Africa may rely on donor projects to fund their activities leading to inconsistent performance. This can create a vicious loop because without showing results it is difficult for the pooled procurement mechanism to justify additional funding from participating countries or incentivize them to move forward with in-country policy and regulatory reform. On the other hand, global pooling arrangements tend to show more consistent results and growth as their internal structures are less complex and may have an advantage in that funding conditions tie countries into using the mechanism. As a country considers engaging with a joint purchasing mechanism, it should review the mechanism's history and consider the distinct difference between global and regional pooled mechanisms.

- *Technical support to countries is needed for them to effectively engage in pooled procurement.* The advantages of pooled procurement continue to be articulated but there is little acknowledgment that countries need support to prepare to participate in pooled procurement mechanisms. One key function of a pooled procurement mechanism should be to assess the differential capacity among countries and build all countries up to an agreed level. This need is often neglected until a mechanism attempts to implement pooled procurement and then falters due to different country readiness levels. Pooled procurement mechanisms, especially regional ones, should state the benchmarks that member states need

to achieve to make the mechanism function effectively. For a country like Botswana looking to engage in pooled procurement, key technical staff should engage with the mechanism on how capacity gaps will be filled and in what timeline. This will enable the country to develop short and medium-term plans to embed pooled procurement within its national procurement cycles.

- *Pooled procurement increases country access to essential medicines and supplies but does not solve in-country distribution challenges.* The literature emphasizes one of the benefits is the increased availability of quality essential medicines at lower prices. In SSA where countries face an influx of sub-standard and fake medicines, this benefit cannot be downplayed as it means the reduction in low-quality medicines that rely on low prices to thrive. However, countries need to recognize that to fully benefit from pooled procurement, changes need to be made to streamline in-country distribution mechanisms for the population to benefit. Therefore, Botswana will need to continue working on supply chain strengthening to maximize the efficiencies generated through pooled procurement.

- *Countries facing transitions need more platforms to share experiences.* This report showcases experiences from many country contexts and common lessons on pooled procurement to consider. Upon review, the research team could not identify a learning exchange or platform that supports experience sharing on pooled procurement. For countries such as Botswana that are facing multiple transitions and economic pressure to increase efficiency in the health sector, it would be beneficial to have a way to systematically engage with other countries and regions that have experience joint purchasing. This would allow the country to share learnings as it ventures into pooled procurement and the associated policy and regulatory reform.

3.5 Botswana stakeholder reflections

3.5.1 Status of current health commodity procurement systems

To understand the context of health commodity procurement in Botswana, the research team focused on two main aspects; the current procurement systems and the challenges faced by key actors. Respondents shared insights on how Botswana finances procurement, the entities involved, and the mechanisms. The GoB provides most funding for health commodity procurement and financial resources are readily available to procure the needed supplies due to political support for the health sector. MoHW, primarily through CMS, is the procuring entity for many health commodities and is responsible for forecasting commodities for a given period, initiating the procurement requests, selecting suppliers, ensuring receipt of the supplies, and overseeing the delivery to health facilities. A few exceptional examples were cited where program teams overseeing specific disease verticals initiated a procurement request for specific commodities.

Health commodity procurement in the public health sector is governed by the Public Procurement and Asset Disposal Act (PPADB Act),[81] which is legislation that applies to all procurements in the public sector. There are no specific regulations for health-related procurements. Within the public procurement system, there are several mechanisms available for procurement and respondents cited three mechanisms - open tenders, selective tenders, and direct procurement. Open tenders can be used for domestic and international suppliers. These tenders are the norm and require a waiver to undertake direct and selective tenders, which respondents said were used for emergency procurements.

Due to challenges in forecasting, quantification, and incomplete orders, the health sector makes a relatively high number of emergency orders. The PPADB Act requires that each type of tender be advertised for a minimum amount of time. For example, direct and selective tenders must be advertised for at least 14 days. There are also varying financial thresholds for each type of tender with direct and selective tenders capped at 25 million Botswana Pula (USD 2,300,000). The adjudication committees and PPADB oversee the tendering process depending on the financial volume of the transaction. One respondent characterized the procurement regulations as open and stated that this transparency acts as a counterbalance to the preferential selection of suppliers. There are multiple existing preferential schemes in Botswana that aim to incentivize local suppliers and manufacturers. Some of the preferential schemes cited by interviewees were the Economic Diversification Drive and the Citizen Owned Empowerment Policy.[82]

All entities responding to the public tenders must be registered with the PPADB. Additionally, to be eligible to supply health commodities in Botswana, the supplier/manufacturer or their local distributor must be registered through the Botswana Medical Regulatory Authority (BoMRA). Due to the limited number of distributors and suppliers currently registered by BoMRA, Botswana often pays prices dictated by suppliers as there is little competition allowing the suppliers to quote high prices. The requirement to register within Botswana impedes market entry by global manufacturers and leads to many intermediaries in the procurement process. According to some respondents, due to Botswanas' relatively low volumes orders, there are limited incentives for global manufacturers and regional suppliers to obtain local registration.

Once a supplier is selected, the health sector often uses a two-to-three-year contract. However, respondents noted challenges in implementing these agreements. Initially, due to preferential schemes, the government selected locally owned suppliers despite not having connections with manufacturers of the health commodities they sought to supply. The limited capacity of local suppliers to deliver orders in full and on time led to sustained shortages of essential medicines because the tenders were running over multiple years. In response to this challenge, the MoHW required a letter of support from global manufacturers and introduced letters of commitment as initial documentation to suppliers. Only once suppliers demonstrated they had secured the relevant stock would they be provided with a proforma invoice to allow payment.

[81] Government of Botswana Public Procurement, and Asset Disposal Act. 2001

[82] Government of Botswana, "Economic Diversification Drive: Medium to Long-Term Strategy, 2011 – 2016."

Within the current procurement system, respondents cited several constraints that lead to shortages and high prices of medicines and medical supplies. The most cited constraints include:

- √ Limited local availability of health commodities due to limited local manufacturing, despite the existence of incentive schemes such as the Economic Diversification Drive to promote local manufacturing.
- √ Preferential schemes that support local suppliers and entities registered in Botswana led to the selection of suppliers that may not have the ability to deliver on time and completely.
- √ Due to Botswana's relatively low order volumes, there are limited incentives for global manufacturers to invest in market entry.
- √ Lack of efficiency in the procurement system.

There are also gaps supply chain management data with some respondents noting challenges in capacity across the health sector to ensure accurate forecasting and quantification of medical supplies needed for each period. The challenges are amplified by the fact that there is limited use of technology in the health procurement process, with health facilities collating their orders manually and the Botswana CMS processing multiple orders and tracking deliveries manually. One respondent noted that the CMS team manually manages an average of 4,000 contracts with suppliers without information technology support through an electronic contract management platform.

Several government institutions are involved in ensuring adherence to procurement regulations and the quality of procured medical supplies. Apart from Botswana CMS and BoMRA, the Botswana Bureau of Standards was highlighted as a key actor. Some respondents noted that communication and alignment among these institutions could be improved. One example was the process of receiving a waiver for international suppliers who are not registered in Botswana but are identified by global pooled procurement mechanisms to supply required commodities. The waiver process requires communication between CMS that liaises with the pooled procurement mechanism and BoMRA to waive the requirement, thereby, allowing the transaction to advance. According to one respondent, the approval of these waiver requests often takes several weeks.

The COVID-19 pandemic has also pressured Botswana's health procurement system. Since Botswana imports most health commodities, pandemic-related factory closures in countries such as China and India adversely impacted the availability of orders beginning in early 2020. Additionally, strict travel restrictions across the globe led to challenges transporting commodities. Several respondents shared that freight costs in 2020 increased and emergency orders were delivered by air (as opposed to shipping and overland freight), which is more expensive. Therefore, Botswana experienced significant price increases on key health commodities due to the COVID-19 travel restrictions and production challenges.

3.5.2 Benefits of pooled procurement

With Botswana in mind, stakeholders provided insights on the potential benefits of pooled procurement. The most cited benefits were better prices, reduced stockouts, improved information flow, assured quality, and economies of scale. Noting that by being part of a pooled procurement arrangement, Botswana could benefit from better-priced health commodities due to increased price transparency and/or increased buying and negotiating power of the pool. Some additional cost efficiencies cited by respondents included reduced freight costs, especially if the pooled procurement mechanism was regional since the commodities would be delivered in bulk to a regional hub in Southern Africa. Botswana would, therefore, not need to arrange freight and handling of small quantities, as is the present case. One respondent also noted that the country could benefit from reduced storage costs if the pooled procurement mechanism allowed Botswana to draw down commodities stored in a regional hub as needed.

Multiple stakeholders noted that pooled procurement could reduce stockouts. The mechanism arrangements usually include turnaround time agreements, assuring on-time delivery. Timely, reliable delivery will, in turn, lead to improved forecasting and planning, resulting in reduced emergency orders and stockouts.

In a pooled procurement arrangement, the country engages one entity that manages the mechanism. Respondents thought this would improve information flow as CMS would be engaging with fewer suppliers and actors in the procurement process and reduce the number of intermediaries, which would also ease communication and information flow. Some said Botswana could receive assurance of the medicines and medical supply quality by engaging in regional or global pooled procurement mechanisms because they often engage global manufacturers that are WHO pre-qualified suppliers. Moreover, pooled procurement may decrease the corruption that is often present in procurement systems. Overall, these benefits would result in efficiencies and economies of scale that Botswana cannot achieve when it procures medicines and medical supplies through the national procurement system.

3.5.3 Barriers to pooled procurement

Engaging in pooled procurement requires shifts in the current systems and processes within Botswana. Respondents were asked to share their perspectives on the barriers that Botswana may face should the country decide to increase the pooled procurement of essential medicines. The main issue highlighted specific regulations and policies that do not align with the requirements of joint purchasing/pooled procurement schemes. Respondents pointed out that Botswana currently lacks legal frameworks related to pooled procurement, which creates a lack of clarity around the types of contracts allowed, the applicable laws, and responsibilities for different stakeholders related to pooled procurement.

Interviewees also noted the need to align Botswana's procurement regulations with those of other countries involved in regional pooled procurement mechanisms such as the SADC region. For example, with the Tanzania Medical Stores Department running the SADC Pooled

Procurement Service, it is unclear which country's procurement regulations to follow when issuing tenders. Lack of clarity in roles may hinder progress towards pooled procurement. One respondent highlighted that Botswana is yet to delegate a contact person for the regional pooled procurement mechanisms in which it is eligible to participate. Without designated focal points, it is difficult for Botswana to effectively share information on its procurement needs with other nations or with global institutions, which is a foundational aspect of pooled procurement.

Additionally, existing country level arrangements, such as preferential schemes that seek to promote procurement from local suppliers and manufacturers, were noted to be a pooled procurement barrier. Interviewees noted that there is no clarity or regulations on balancing these incentives with the need to secure competitive pricing through global or regional procurement. Given that these preferential schemes, such as the Economic Diversification Drive, were instituted by political leadership, respondents noted the need to increase advocacy with politicians on the benefits of pooled procurement.

In general, the lack of basic procurement knowledge among the public and leadership, including those in the health sector and political leaders who usually lean towards protecting the citizen empowerment interest, constitutes a significant barrier to moving towards pooled procurement. Several interviewees noted the resulting lack of clear leadership needed to drive the pooled procurement process forward. High turnover in government leadership has also complicated matters, as sensitization among current leaders may not guarantee continuity in the process.

There is a need to build trust between Botswana and other actors involved in pooled procurement schemes. Several respondents cited the issue of pre-payments which are required by most pooled procurement mechanisms. Botswana's procurement regulations only allow for payment after delivery which can hinder involvement in a pooled procurement. Once pre-payments are approved, respondents noted that it takes several weeks for the government to transfer funds to the institution managing the pooled procurement mechanism which can result in delayed delivery of required commodities.

Concerning drug policies, respondents emphasized that the lack of harmonization in treatment regimens, essential medicines, and dosage forms within the region could hinder regional pooling efforts. Countries operating as a single bloc to consolidate orders and make bulk purchases is a key tenet in regional pooled procurement. One stakeholder highlighted that Botswana tends to adopt new regimens more quickly than its neighboring countries, taking ARV regimens and guidelines as an example. If Botswana does not require similar medicines to other countries in the region, it will be impractical for them to consolidate medicine purchases. In addition, a few respondents noted that not all the countries that neighbor Botswana are at the same level regarding systems, infrastructure, and practices related to procurement, which might complicate the establishment of a successful pooled procurement mechanism in the region.

3.5.4 Current and potential pooled procurement mechanisms for Botswana

One of the research objectives was to gain insights on how to contextualize and operationalize pooled procurement in Botswana. The research team investigated the historical pooled procurement arrangements Botswana has engaged and the learning from these experiences. Additionally, the team considered current pooled procurement mechanisms that Botswana is using to identify successes and opportunities for scaling up these mechanisms. Respondents cited a range of examples of potential pooled procurement mechanisms, from global and regional pooled procurement arrangements to mechanisms run by projects including the WHO Global Drug Facility, UNICEF's pooled procurement mechanism, GFATM, SADC Pooled Procurement Services, and USAID's Global Health Supply Chain Program.

Botswana has used some of these mechanisms to purchase HIV commodities (GFATM and UNICEF) in addition to TB medicines (GFATM). While WHO's Global Drug Facility has enabled the country to procure medical commodities across several disease areas and diagnostic equipment, UNICEF's pooled procurement has supplied vaccines and nutritional supplements for maternal and child health programs. Botswana is currently in discussions with SADC to ensure alignment in regulations to potentially move forward with using this mechanism. Additionally, some of the current global pooled procurement mechanisms have the potential to be used for a wider variety of products. One example cited was the UNICEF pooled procurement mechanism that could avail additional commodities to Botswana.

3.5.4.1 Key legal, regulatory, and institutional frameworks that would need to be established

Given that a supportive legislative and regulatory environment is key to the success of any supply chain initiative, respondents identified legal, regulatory, and institutional frameworks that need to be in place or updated for pooled procurement to be successful in Botswana. Respondents noted that all laws and regulations that govern procurement, including supply, audits, and payments, need to be reviewed and updated, including the Public Finance Management Act, the Public Procurement and Assets Disposal Act, and the Internal Audit Law. Additionally, stakeholders stressed updating the citizen empowerment law as it relates to medicines. Stakeholders suggested that preference for local suppliers should not apply to medicines with no adequate or reliable local manufacturing capacity. Additionally, respondents noted that it would be important to de-link the medicine procurement law from the general procurement law and have a separate law to regulate the procurement of medicines, with clear provision for pooled procurement. One stakeholder noted that the challenge with the current procurement law is that it was not developed for medicines, which are very specific with unique features and needs do not apply to other commodities, as a result the current law hinders access.

3.5.4.2 Best practices

Respondents identified best practices that Botswana could adopt to access or benefit from pooled procurement mechanisms; practices included developing procurement expertise; internal coordination; standardization of procurement process between different programs and

CMS; and collaborating and benchmarking to drive continuous improvement. Respondents emphasized that the lack of procurement knowledge and skill in Botswana creates the need for continuous awareness creation, training, and skill building for procurement implementation. Furthermore, respondents noted the need for better collaboration and agreement on procurement practices, including quantification, forecasting and communication across the different programs to ensure better planning for country needs.

As highlighted, twinning and benchmarking are best practices that Botswana could also adopt. To gain a clear understanding of pooled procurement's real costs and benefits, practices from other regions should inform Botswana reforms. Another quality assurance best practice for medicine would be adopting international standards for vetting vendors, such as WHO's list of pre-qualified suppliers, and using post-market surveillance to strengthen quality control and monitoring commodities brought into the country. Additionally, Wambo, a GFATM online procurement tool that partially automates procurement by allowing countries to place orders online, was also cited as best practice.

The only alternative identified by respondents that could provide better or comparable benefits to pooled procurement was cutting out the intermediary and buying directly from manufacturers. Respondents noted this would solve some challenges that the country is having with suppliers, including goods not being delivered on time resulting in increased efficiency in the distribution channel and cost savings. However, some of the challenges with the local regulations, like the citizen empowerment law, might still apply.

3.5.4.3 Analysis of local pooled procurement reflections by stakeholders

The decision on whether to increase the use of pooled procurement in Botswana has strategic dimensions and trade-offs. To synthesize the statements from stakeholders, the research team selected the SWOT Analysis framework to understand Botswana's procurement system for health commodities. The results will support a systematic reflection on the current internal competencies and external factors to manage for Botswana to benefit from pooled procurement mechanisms.

Table 5: SWOT analysis of key findings from stakeholder interviews on Botswana's procurement system for health commodities

Strength	Weakness
○ Political support and investments in the health sector ○ Fiscal space to determine the best procurement mechanism - economies of scale due to pooled procurement outweigh the additional costs with average savings of 40% obtained in the past when using pooled procurement ○ Clear institutional mandates – current roles that the CMS, BoMRA, and the Bureau of Standards play in the procurement process	○ Effect of preferential schemes on supplier pool - preferential schemes that are designed to increase local manufacturing and employment opportunities ○ Limited capacity of some local suppliers - inadequate technical and financial capacity to fulfill the orders ○ Lack of health sector-specific procurement regulations - PPADB Act requires all suppliers to be registered in Botswana, but due to low order volumes the number of international manufacturers and suppliers have limited incentives to register in the country ○ Low coordination between key institutions leading to delays in completing the procurement ○ Limited integration of international procurement and supply chain best practices (WHO pre-qualification) into Botswana's health medicines and other health commodity procurement processes ○ Wide span of roles at CMS – there is a need to consider requirements that suppliers deliver to regional hubs or large facilities thereby reducing the logistics that CMS is required to manage ○ CMS Limited technical capacity - challenges in forecasting and quantification ○ Manual procurement systems - With the CMS team managing 4,000 contracts without an electronic platform, they are unable to effectively track supplier performance
Opportunities	**Threats**
○ Current demand for a more effective and efficient procurement process to combat unreliable medicine supplies and improve efficiency ○ Support for locally manufactured medicines by the GoB through the availability of various economic incentives to encourage local manufacturing. ○ Already existing regional or global procurement bodies with evidence of positive results in Botswana ○ Capacity building institutions readily available - Various organizations are readily available to build technical capacity in procurement-related areas.	○ Uncertainty in future developments in regulatory frameworks – successfully establishing a pooled procurement mechanism in Botswana might be compromised if the current legislation is not reviewed to reflect the needs of pooled procurement ○ Resistance to change from various stakeholders ○ Absence of broad public support - lack of knowledge and awareness of the pooled procurement process benefits and function fuels the absence of public support ○ Supply chain issues that are unrelated to pooled procurement - inefficiencies created by poor procurement infrastructure and systems such as issues with data quality leading to poor forecasting and possible wastage or stock out which reduces the visibility of the benefits of pooled procurement

4.0 Key takeaways and considerations for Botswana

Following the review of global and regional pooled procurement mechanisms and an analysis of the reflections from select country stakeholders, Botswana will need to review the evidence and make strategic decisions on advancing pooled procurement. These decisions include identifying the type of pooled procurement mechanism to invest in, understanding how to prioritize the procurement reforms required to maximize their benefits, and knowing how to support the health system documents learning.

1. Strategic decisions: Global or regional pooled procurement

As Botswana decides how to advance pooled procurement, a ***key decision is to use global or regional mechanisms***. The global mechanisms reviewed are fully operational as they are administered by international agencies. There are several global pooled procurement mechanisms that Botswana can access as an upper-middle-income country. Some of these global mechanisms include the UNICEF pooled procurement and WHO's Global Drug Facility which the country already uses or has used.

Conversely, Botswana can engage in the SADC Pooled Procurement Service. This is a mechanism that the country has no experience using. As the SADC pooled procurement mechanism is in its early stages of operations, Botswana should be aware that ***investment is required to support the administration and efficient functioning of the regional service***. Therefore, there may be a lag time before the country can benefit from regional pooled procurement compared to global pooled procurement services.

There may be greater benefits in using a combination of global and regional mechanisms. Apart from the benefits of better pricing, a ***regional pooled mechanism could provide market access to Botswana's fledgling pharmaceutical and medical supply manufacturing industry*.** Therefore, Botswana should consider engaging deeper SADC Pooled Procurement Service due to the additional economic benefits that align with the country's Economic Diversification Drive goals.

2. Harmonization and realignment

For regional pooled procurement mechanisms to function optimally, participating countries need to operate on similar standards on areas such as common essential medicine lists and medicine regulation policies including those related to medicines registration, import, and export of medicines and commodities, pharmaceutical usage, and treatment guidelines. For Botswana to benefit from the SADC regional mechanism, **the country will need to** develop a roadmap to achieve harmonization and alignment. Within the SADC region, while progress has been made on medicine regulation, there is a need to harmonize procurement regulations to facilitate the operationalization of the regional pooled procurement service.

As Botswana seeks to expand the utility of global pooled procurement services, the country will need to ***take another look at its procurement regulations concerning international suppliers***. Current regulations act as disincentives for international suppliers. While the country's economic policies seek to protect local industry, this may result in missed opportunities with international

supplies selected by global pooled procurement partners. By requiring all suppliers to register in Botswana and failing to provide a clear method to facilitate waivers to unregistered suppliers that offer quality products at competitive prices, the country risks limiting its ability to benefit from pooled procurement. Therefore, to access international suppliers providing products at competitive prices, Botswana's health sector should advocate for a review of all procurement regulations.

One of the strengths identified in the SWOT analysis was that the Botswanan key institutions involved in procurement have clear mandates. However, these institutions need to communicate more efficiently to ensure bureaucratic processes do not create delays in purchasing medical commodities. ***Realignment between key institutions,*** such as CMS and BoMRA, may be achieved by establishing joint working groups to develop standard operating procedures and workflows for critical components of the procurement process for medical commodities.

3. Technical capacity and integrating best practices

Botswana needs to address its current legal, technical capacity, and social challenges while also adopting some best practices to reap the maximum benefits of pooled procurement. Both stakeholders and interviewees identified key organizations that can build the capacity of Botswana in pooled procurement. Furthermore, local pharmaceutical suppliers and research institutions were noted as key groups that could provide capacity building support.

Stakeholders identified forecasting and quantification as two areas that Botswana's health sector needs to strengthen. For countries to manage their procurement and supply chain, accurate and timely data on historical consumption, and projected demand of essential medicines and medical supplies are necessary. Additionally, it was noted that Botswana needs to rapidly supply COVID-19 vaccines, when available, to create an urgency for those technical capacities to be improved.

Furthermore, Botswana could ***integrate global best practices in procurement and supply chain management*** as one strategy to increase efficiency in the health sector. Examples of these best practices include selecting suppliers with adequate technical capacity by requiring that all suppliers be pre-qualified by the WHO and focusing on the quality of medicines and medical supplies procured. Some interventions proposed to enhance quality include routine post-market surveillance of products that are part of the essential medicines list.

Collaborating, benchmarking, and learning from other countries' experiences through information exchange and study tours to share lessons learned in pooled procurement is an additional best practice that Botswana should consider facilitating at the technical and political levels.

Integrating technology into the procurement processes is one other area where Botswana should invest. Stakeholders noted manual management of multiple contracts limits CMS

effectiveness in tracking the performance of suppliers and using collated data to make evidence-driven procurement decisions. Therefore, Botswana should consider introducing procurement technology platforms for the health sector.

4. Learning by doing

Pooled procurement is an evolving area, and there is still much to learn. For countries such as Botswana that are looking to expand the use of regional and pooled procurement mechanisms, it is important to track progress and document learnings. As an upper-middle-income nation seeking to enhance efficiency in its health sector, pooled procurement is a complementary approach that could support a reduction in costs and access to higher quality products. Documenting strategic decisions such as how much to procure and process changes undertaken to align country systems will be useful evidence for other countries looking to use pooled procurement mechanisms, especially those facing transitions from donor-funded procurement programs.

5. Advocacy through civic engagement and awareness

Continuous public support and political commitment are critical to ensure the successful establishment of a pooled procurement mechanism. However, stakeholders acknowledged that the lack of knowledge and awareness of the procurement process lessens support. Therefore, ***GoB and other supportive international and local capacity-building organizations will need to take the initiative to educate the public on the basic principles of procurement to prevent misunderstandings that might create opposition to the process.*** The numerous benefits of pooled procurement, including cost savings, price benefits, and access to higher-quality medicines, can be used as advocacy arguments to create a conducive and supportive environment for pooled procurement.

6. Harmonization between international and donor procurement agencies.

Although the availability of numerous procurement agencies is an advantage to Botswana, ***GoB should consider installing a mechanism to harmonize and synergize various pooled procurement efforts, including in technical capacity building, from various partners in the country.*** Harmonization could be done through either having regular government-led or donor led coordination meetings to prevent duplication of efforts. Specifically, BoMRA should lead in harmonizing the Essential Medicines Lists and Standard Treatment Guidelines to attain a wider range of products to select for pooled procurement.

5.0 Conclusions and Recommendations

5.1 Conclusion

Pooled procurement is a complicated process that requires relationships across member states, ministries, suppliers, and end-users. While many barriers impede successful pooled procurement processes and activities, many promising practices address the challenges. As an upper-middle-income nation seeking to enhance efficiency in its health sector, pooled procurement is a complementary approach that could support a reduction in costs and access to higher quality

products in Botswana. There is a need for the MoHW to adopt a phased approach with tangible objectives across the four levels of pooled procurement. The phased approach will allow continuing use of global mechanisms such as GFATM, UNICEF, UNFPA, WHO, and PEPFAR while reinforcing information sharing through SADC Pooled Procurement Services and expanding regional coordination. It is crucial to understand that even seemingly lower levels of collaboration that only involve information sharing are beneficial.

This study has highlighted and confirmed that "pooled procurement" of medicines and other related products goes beyond the acquisition or purchasing of products. It relies on the efficiencies of the various supporting structures and systems for a successful and sustainable joint procurement system. These systems and structures provide an enabling environment for smooth adoption and an effective and sustainable implementation process.

5.2 Recommendations

Recommended areas of improvement and strengthening before implementing pooled procurement are as follows:

- Educate stakeholders and the public on pooled procurement by using the benefits[83] as an advocacy tool to prevent misunderstandings that might create opposition to the process.
- Strengthen CMS capacity for forecasting and quantification of needs, assessment of supplier performance, and increased collaboration and information sharing.
- Prioritize harmonization of medicine registration procedures and processes for pooled procurement. Specifically, harmonizing the Essential Medicines Lists and Standard Treatment Guidelines should obtain a wider range of products.
- Fast-track registration processes by giving due consideration to suppliers who meet international standards, such as being WHO pre-qualified, in assessing waiver requests.
- Transfer and build upon the existing national procurement management capacity and skills to support joint purchasing mechanisms.
- Strengthen legal and regulatory statutes to ensure that the government adequately funds the purchase of medicines. These legal provisions can take the form of a) mandated budget line, b) specific allocations “ring-fenced,” or c) protected for medicines procurement.
- Conduct a detailed study to assess the current capacity of local manufacturers to address needs for pooled procurement in terms of medicine selection, volumes, and quality, in addition to identifying their potential role in regional pooled procurement and mapping.

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[83] **Price benefits include** achieving economies of scale, maximizing the use of already limited resources, and sharing price information/price referencing. **Non-price benefits include** universal benefits within public health perspectives, harmonization (standard treatment guidelines, prequalification of suppliers, etc.), confidence-building with purchasers and suppliers, common standards of quality within quality assurance, rationalizing of procurement processes, political compatibility.

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Annex 1: Selection Criteria Matrix

Details	Botswana	Algeria	Gabon	Libya	Mauritius	Namibia	South Africa	Equatorial Guinea*
Country characteristics								
Per capita GDP (USD), ***WB (2018)***	8259.0	4115.0	7953.0	7242.0	11239.0	5932.0	6374.0	10255.0
Population (million), ***WB (2018)***	2.3	42.2	2.1	6.7	1.3	2.4	57.8	1.3
Urban as % of **population, *WB (2018)***	69.4	72.6	89.4	80.1	40.8	50.0	66.4	72.1
Health market **structure**								
Current total health expenditure (% of GDP**), *WB (2016)***	5.46	6.65	3.11		5.75	9.12	8.11	3.38
Domestic general government health expenditure (% of GDP***), WB (2016)***	3.06	4.50	2.01		2.53	5.65	4.36	0.79
Domestic general government health expenditure per capita (current US$), *WB (2016)*	212.50	176.27	142.32		243.98	249.29	230.06	66.16
Out-of-pocket expenditure per capita (current US$), *WB (2016)*	19.94	80.42	49.61		266.38	31.09	33.19	204.94
Out-of-pocket expenditure (% of current health expenditure), *WB (2016)*	5.25	30.88	22.51		48.16	7.72	7.75	72.83
Health Indicators								
Incidence of malaria (per 1,000 population at risk**), *WB (2017)***	1.97		168.87		..	44.56	3.97	343.26
Incidence of **tuberculosis (per 100,000 people), *WB (2018)***	275	69	525	40	13	524	520	201
Antiretroviral therapy coverage **(% of people living with HIV), *WB (2018)***	83	81	67	44	22	92	62	34
share Adults (ages 15+) living with HIV (2018)**, *WB (2018)***	24%	0%	4%	0%	1%	12%	18%	7%
Geography (Region)	S. Africa	N. Africa	Central Africa	N. Africa	E. Africa	S. Africa	S. Africa	C. Africa
Scores		6	11	3	5	13	18	9
Selected		YES	YES	NO	NO	YES	YES	YES

Source: World Bank (2016, 2017, 2018)

Explanatory note: While Equatorial Guinea received a score that would have allowed it to be reviewed for a country case study, subsequent analysis showed that its high per capita income might have skewed the weighting and total scores. While Equatorial Guinea has a high per capita GDP, it has high levels of corruption and inequity that result in some of the poorest health indicators in sub-Saharan Africa. Therefore, the research team concluded that there would be limited benefit in developing a case study on this country.

Annex 2: Interview Guide

QUESTIONS

Interview No: Respondent Name(s):

Organization(s): Date:

Section 1: Procurement of medicines and medical supplies in Botswana

1. What are the current available procurement systems that exist in Botswana?
2. *In your opinion:*

   1.1 What are the main challenges Botswana faces with regards to procurement of essential medicines? *(Prompt: Efficiency, Effectiveness, User friendliness or PESTEL (Political, Economic, Social Technology, Environment, and Legal Barriers))*

   1.2 What are some of the benefits of moving towards pooled procurement in Botswana? (*Prompt: Cost-savings, efficiency gains, etc.)*

   1.3 What are some of the barriers of moving towards pooled procurement in Botswana?

   1.4 What are some of the pooled procurement mechanisms that Botswana could benefit from?

Section 2: Current Landscape of Pooled Procurement Mechanisms in Botswana

3. Are you aware of any pooled procurement arrangements that Botswana previously engaged in? Yes | No

   2.1 If yes which one/s?

   2.1.1 Were there any benefits in implementing these pooled procurement mechanisms?

   Yes | No

   2.1.1.1 If Yes, what were the benefits?

   2.1.2 Were there any challenges in implementing these pooled procurement mechanisms?

   Yes | No

   2.1.2.1 If Yes, what were the challenges?

   2.1.2.1.1 How were the challenges addressed?
4. What are some of the pooled procurement mechanisms your organization has worked on/has experience in?
5. **FOR UNICEF ONLY** - The Government of Botswana Has used UNICEF's pooled procurement arrangements for vaccines in the past. Can there be widened to include other medicines and commodities?

Section 3: Future Pooled Procurement Mechanisms in Botswana

6. What institutions/organizations in Botswana would provide capacity to the Government of Botswana to successfully adopt and implement pooled procurement? (*Prompt: WHO, World Bank, USAID)*

7. What are the legal, regulatory, and institutional frameworks that would need to be in place or updated for Botswana to engage in pooled procurement?
8. What are some alternatives to pooled procurement that Botswana should consider improving the procurement of medicines and medical supplies?
9. Based on your research and experience what best practices should Botswana adopt to access/benefit from pooled procurement mechanisms?
10. In your opinion, what regional mechanisms for pooled procurement of medicines and medical supplies could Botswana benefit from as an upper middle-income country?
11. In your opinion, are there some global pooled procurement arrangements that you think Botswana could benefit from?
12. **FOR MOHW/CMS ONLY:** In order to implement pooled procurement of essential medicines in Botswana, what areas of support would you need? *(Prompt: financial support, infrastructure, regulatory, human capital or expertise etc.)*
13. **FOR PWC ONLY:**
    a. Based on your experience in Botswana (and beyond), what are the efficiency gains that can be accrued as a result of using a pooled procurement mechanism?
    b. Apart from procurement of TB commodities, are there other opportunities for Botswana to benefit from the GFTAM pooled procurement mechanism
14. **FOR SADC ONLY:**
    a. What is the status of pooled procurement of medicines and essential commodities within the SADC region?
    b. What have been some successes in the past, with regards to pooled procurement in the region?
    c. What are some of the challenges hindering SADC countries from engaging in pooled procurement of medicines and other essential commodities?
    d. As a SADC member country, are there criteria that Botswana needs to fulfill in order to benefit from pooled procurement arrangements managed by SADC?
    e. In which ways is SADC supporting harmonization and improvement of the policy and regulatory environment for procurement among its member states?
    f. Are there other successful regional bodies that SADC is looking to learn from, with regards to pooled procurement?

Section 4: Conclusion

10. Do you have any other comments?
11. Are there any other stakeholders with insights on pooled procurement that we should speak to?

Annex 3: Country Case Studies

ALGERIA

Algeria meets about half of the essential medicine demand from within the country's manufacturing, as there are over thirty drug producers in country.[84] Not only are there a plethora of drug producers, but Algeria also has the largest pharmaceutical market in Africa, valued at 3.7 billion USD. The government of Algeria wants to be able to meet 70 percent of this demand by 2021, so there is an obvious focus on increasing local capacity.[85] To encourage local manufacturing, Algeria prohibits importing any drug that can be manufactured locally. Still, Algeria imports 12 million USD worth of Chinese pharmaceutical products (34 percent active pharmaceutical ingredients, 20 percent hospital diagnostic equipment, 9 percent formulations) a year with a growth rate for imports of around ten percent.[86]

The Pharmacie Centrale des Hôpitaux (PCH), established in 1994, is the central supplier of medicines for hospitals and pharmacies in the region.[87] In 2018, the National Agency of Pharmaceuticals was founded under the Ministry of Health to register, approve, and control pharmaceutical Algeria's products. The establishing article states that, "the State shall ensure the availability of pharmaceutical products and medical devices, and guarantee access to essential medical products and devices at all times and in all places within the national territory."[88]

The government has also shown interest in exploring pooled procurement mechanisms, particularly with partnerships within Africa. In 2019, Algeria agreed to build pooled procurement mechanisms by sharing information around vaccine purchasing practices with eight other middle income-countries (Algeria, Botswana, Cabo Verde, Kingdom of Eswatini, Gabon, Mauritius, Namibia, São Tomé and Príncipe and Seychelles). This agreement took place at a workshop organized by the WHO Regional Office for Africa. The agreement hopes that the countries will share information and lead to joint price negotiating or even pooled procurement mechanisms in the future.[89] There has been no public update since this workshop. Although the government desires to use local production to meet demand, it has been challenging to meet that demand with local production. Algeria has explored additional procurement mechanisms. In 2017, as part of its work with the Ministry of Health, UNFPA Algeria consulted on a project that encouraged the use of their procurement services (UNFPA PSB) to procure contraceptive products. In that year, the Central Pharmacy of Hospitals of Algeria requested that the Algeria country office

[84] Kaddar et al., "Vaccine Procurement in the Middle East and North Africa Region."
[85] Oxford Business Group, "Import Replacement Benefits Algeria's Pharmaceuticals."
[86] UNAIDS and CCCM HPIE, "21 Country Profiles An Introduction to Local Pharmaceutical Production Opportunities in Africa."
[87] PharmaBoardroom, "Pharmacie Centrale Des Hôpitaux (PCH) – M'Hamed Ayad, Director General – Algeria."
[88] Slimani, "Bill on Health."
[89] World Health Organisation, "Nine African Countries Agree to Begin Journey towards Pooled Procurement to Increase Their Access to Affordable Life-Saving Vaccines."

procure these products through the UNFPA.[90] It is unclear if this procurement continued, as there is no formal procurement relationship with UNFPA and procurement agencies in Algeria.

In Algeria, procurement entities charge Ministries of Health high revenue-earning margins. These profits discourage the Ministry to deploy any mechanisms to stabilize or reduce vaccine prices.[91] Algeria is also part of the African Medicine Regulatory Harmonization scheme, which would allow for stronger collaboration and partnerships within the region because of similar regulatory environments.[92] With resistance to refocusing priorities, the country often experiences stockouts because of its inability to keep up with the growing population and their needs.[93] On the other hand, given this situation, particularly with a burgeoning population, Algeria needs to find another way to procure medicines and be the perfect place to examine pooled procurement agreements. With the involvement in the 2019 agreement, the government has expressed some interest in exploring the possibility. However, there is still a strong focus on internal production that may discourage pooled procurement mechanisms that rely heavily on external vendors.

GABON

Gabon is an upper-middle-income country in Central Africa with a population of 2.2 million people, whose per capita income is four times higher than the average sub-Saharan African country.[94] There are, however, high levels of inequity with a third of the population living below the poverty line.[95] Gabon has a National Health Insurance and Social Guarantee Fund established in 2007, Caisse Nationale d´Assurance Maladie et de Garantie Sociale (CNAMGS).[96] CNAMGS administers three schemes – a non-contributory one for economically vulnerable Gabonese (Gabonais économiquement faible, GEF) and separate contributory social protection schemes for the civil service and the private sector whose benefits include compulsory health insurance.[97] The national health insurance scheme has been a significant driver of increased health spending. Despite rising health expenditures over the past decade, Gabon has poor health outcomes in comparison with other upper-middle-income countries.[98]

Pharmaceutical procurement is centralized through a national procurement office, Office Pharmaceutique National (OPN), which is responsible for purchasing and distributing medicines and pharmaceutical supplies to all hospitals in Gabon. In 2013, pharmaceutical spending represented 25% of Gabon's total health expenditure. However, inefficient distribution systems have led to health facilities purchasing medicines and medical supplies from other sources to address persistent drug shortages.[99] Of note, half of Gabon's workforce is in the informal sector

[90] "Advocacy for Algeria's Procurement of Commodities."
[91] Silverman et al., "Tackling the Triple Transition in Global Health Procurement."
[92] Zerhouni, Mohaed Wadie and Fellousse, L. Asma El Alami El, "Moving towards a North African Pharmaceutical Market."
[93] Oxford Business Group, "Import Replacement Benefits Algeria's Pharmaceuticals."
[94] Central Intelligence Agency, "Africa :: Gabon — The World Factbook - Central Intelligence Agency."
[95] The World Bank Group, "Gabon Overview."
[96] Mibindzou Mouelet, El Idrissi, and Robyn, "Gabon Indigents Scheme: A Social Health Insurance Program for the Poor."
[97] World Bank Group, *Gabon Public Expenditure Review*.
[98] International Monetary Fund, "Gabon."
[99] Saleh, Couttolenc, and Barroy, *Health Financing in the Republic of Gabon*.

and therefore ineligible for national health insurance benefits.[100] This group pays out of pocket for healthcare but there is insufficient data on the effect of this private spending on the Gabonese pharmaceuticals market.[101] While Gabon is rich in natural resources,[102] its economic performance is primarily driven by oil production with the country being Africa's fifth largest oil producer.[103] With fluctuations in oil prices, the country urgently needs to increase efficiency in the health sector,[104] including through strengthening its pharmaceutical management system.[105]

Gabon has demonstrated a commitment to sharing information on pharmaceutical procurement through its membership in several collaborative platforms. For example, the country is working with five other countries that are part of the Central African Economic and Monetary Community (CEMAC),[106] with support from the WHO, to strengthen the capacity of its regulatory body on quality assurance and marketing authorization. Through the Regional Sub-Program Harmonization of National Pharmaceutical Policies in Central Africa, Gabon is harmonizing standards with other Central African countries to reduce sub-standard medicines in the region. This is especially important because 90 percent of the medicines available in West Africa are either off-patent medications or older formulations of current products.[107]

The country is a member of Association Africaine des Centrale d'Achats de Medicaments Essentieles (ACAME),[108] which is a membership organization made up of 22 countries from West and Central Africa. ACAME aims to enhance the sustainability of national procurement systems by strengthening the capacity of central medical stores across its member states.[109] Another stated objective for ACAME is to progressively support joint purchasing among its members. In 1998, with support from the WHO-AFRO office, ACAME ran a joint bulk-purchasing pilot for essential medicines on behalf of three member states and the results showed that it was able to secure significantly lower prices than the participating countries had obtained.[110] Subsequently, Gabon participated in working groups established to implement the learnings from this initial pooled procurement experiment.[111] Some of the recommendations from this early pooled procurement work were that members of ACAME needed to establish formal governance structures and for member states to harmonize national procurement policies to reduce joint procurement timelines.[112] ACAME's next pooled procurement support to member states was

[100] World Bank Group, *Gabon Public Expenditure Review*.
[101] Saleh, Couttolenc, and Barroy, *Health Financing in the Republic of Gabon*.
[102] Central Intelligence Agency, "Africa :: Gabon — The World Factbook - Central Intelligence Agency."
[103] The World Bank Group, "Gabon Overview."
[104] International Monetary Fund, "Gabon."
[105] World Bank Group, *Gabon Public Expenditure Review*.
[106] World Health Organisation, "WHO | Strengthening Medicines Regulation in Central Africa."
[107] Silverman et al., "Tackling the Triple Transition in Global Health Procurement."
[108] The Association of Central African Purchases of Essential Medicines, "ACAME - Historical."
[109] Millot, "Access to essential medicines in Africa."
[110] Abdallah, "West Africa Reproductive Health Commodity Security. 'Review of Pooled Procurement.'"
[111] World Health Organisation, "Joint Bulk Purchasing of Essential Drugs - Achats Groupés de Médicaments Essentiels (A.C.A.M.E. - WHO/AFRO, 1999, 28 p.): PART I - *study visit to the secretariats of essential drugs joint bulk purchasing systems in countries of the maghreb and the gulf."*
[112] Abdallah, "West Africa Reproductive Health Commodity Security. 'Review of Pooled Procurement.'"

coordinating informed buying of HIV/AIDS medicines in collaboration with Management Sciences for Health and Rockefeller Foundation, but it is unclear whether Gabon participated.[113] There is limited data on pooled procurement or pharmaceutical system strengthening initiatives in Gabon between 2000 to 2012. This lull in activity coincides with a decade of high oil prices (2001 -2013) that boosted Gabon's economy.[114] Gabon joined other CEMAC member states to adopt a common regional medicines policy in 2013, which is a foundational aspect for pooled procurement.[115] In November 2019, Gabon convened with eight other countries, including five Small Island Developing States, to commit to the establishment of a pooled procurement mechanism for vaccines.[116] This new pooled procurement group is supported by the World Health Organization (WHO) Regional Office for Africa.

RWANDA

Rwanda has only one drug manufacturer in the country and imports over 95 percent of the needed medicines from foreign countries, mainly India, Belgium, and France.[117] Rwanda also has a much smaller market size than its neighbors with a population of around 11 million.[118] In 2014, Rwanda's pharma market size was USD 75 million, in comparison to Kenya with a USD 740 million market or Tanzania at USD 400 million.[119] Rwanda is part of the East African Community (EAC), which focuses on improving regional production capacity. While it may not be feasible to build a large local capacity for drug production, Rwanda can certainly benefit from a regional drug market.[120] The Third Health Sector Strategic Plan (HSSP III) 2012-2018 tried to increase local capacity for drug production, but Rwanda still relies on out of country producers for essential medicines.[121]

The procurement system is not centralized and includes three procurers: Medical Production and Procurement Division (MPPD), referral hospital (Bureau des Formations médicales agréées du Rwanda- BUFMAR), and private pharmacy wholesalers.[122] This decentralization model is modeled after the United Nations Commission on International Trade Law Model Law on Procurement of Goods, Construction and Services (UNCITRAL Model Law), which sets as an example that public procurement systems should have a decentralized purchasing mechanism with a central regulatory agency.[123,124] All public procurement is done through an international competitive

[113] Management Sciences for Health, "Increasing Access to Quality Pharmaceuticals and Other Commodities for the Treatment, Care, and Support of HIV/AIDS Patients: A Case for Regional Collaboration for Procurement."
[114] Central Intelligence Agency, "Africa :: Gabon — The World Factbook - Central Intelligence Agency."
[115] World Health Organisation, "WHO | Strengthening Medicines Regulation in Central Africa."
[116] World Health Organisation, "Nine African Countries Agree to Begin Journey towards Pooled Procurement to Increase Their Access to Affordable Life-Saving Vaccines."
[117] "Rwanda (RWA) Exports, Imports, and Trade Partners."
[118] United National Development Programme, "About Rwanda."
[119] Mohamed, "East African Pharmacetucial Sector: Opportunities and Challenges."
[120] East African Community, "2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027."
[121] UNAIDS and CCCM HPIE, "21 Country Profiles An Introduction to Local Pharmaceutical Production Opportunities in Africa."
[122] http://moh.gov.rw/fileadmin/templates/policies/Pharmacy-Policy_Rwanda-2016.pdf
[123] Arney, Lesley et al., "Strategic Contracting Practices to Improve Procurement of Health Commodities."
[124] United Nationas Commission on International Trade Law, "Status: UNCITRAL Model Law on International Commercial Arbitration (1985), with Amendments as Adopted in 2006 | United Nations Commission On International Trade Law."

bidding process. The import process follows the guidelines of WHO prequalification and approval by the Stringent Regulatory Authority.[125] Before 2011, the Central Medicines Store (CAMERWA) was the Ministry of Health's public procurement arm. The goal of CAMERWA was to procure medicines for public and private hospitals, but hospitals relied heavily on private suppliers. In 2011, the Medical Procurement and Production Division of Rwanda Biomedical Center (RBC) was established and took over public procurement. Additionally, the Rwanda Public Procurement Authority (RPPA) was established to provide oversight on procurement activities. With these changes, the government of Rwanda sought to decentralize procurement activities.[126]

Looking at the regulatory atmosphere of the country and region in terms of drug procurement, Rwanda is part of the EAC and its Medicines Regulatory Harmonization (EAC MRH) initiative, which seeks to strengthen medicines regulatory systems throughout the region. Rwanda leads the working group on Information Management Systems (IMS). However, with Rwanda's weak drug policy regulatory environment, it is difficult for the country to participate in full regional harmonization.[127] In November 2019, at a meeting of the United Nations Economic Commission for Africa (UNECA), the Government of Seychelles representing Small Island Developing States (SIDS), African Union Commission (AUC) and the Intergovernmental Authority on Development (IGAD), the African Continental Free Trade Area (AfCFTA)-Anchored Pharmaceutical initiative was proposed. This initiative has a focus on local drug manufacturing, predicated on the Pharmaceutical Manufacturing Plan for Africa (PMPA), but more relevant, proposes a pooled procurement agreement with Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Rwanda, Sudan, and IGAD (including Ethiopia and Kenya). The representative from the Ministry of Health of Rwanda committed to this initiative at the meeting. A way forward and key next steps were discussed at this meeting, but it is unclear when these will be accomplished, particularly with the COVID-19 situation.[128]

Rwanda is open to pooled procurement agreements with a specific provision in the Rwanda Public Procurement Authority (RPPA) that foresees pooled procurement agreements in the future.[129] However, despite this willingness to explore pooled procurement mechanisms within the region, gaps in the country's policy and regulatory frameworks hinder the advancement of joint purchasing with other countries. One such gap is the lack of an autonomous medical regulatory authority (MRA)[130] which has been cited as a challenge to the harmonization of medicine regulations in the EAC.[131]

[125] Syam, "Regional Pooled Procurement of Medicines in the East African Community."
[126] Syam.
[127] PATH, "Medicines Regulation in the East African Community: Landscape Summary Report."
[128] United National Economic Commission for Africa, "Report of the High-Level Stakeholder Meeting on: The AfCTA: Opportunities for Pooled Porucrement of Essential Drugs and Products and Local Pharmacetucials Productions for the Continent."
[129] UNAIDS and CCCM HPIE, "21 Country Profiles An Introduction to Local Pharmaceutical Production Opportunities in Africa."
[130] WHO/AFRO, "Assessment of Medicine Pricing and Reimbursement Systems in Health Insurance Schemes in Selected African Countries."
[131] PATH, "Medicines Regulation in the East African Community: Landscape Summary Report."

NAMIBIA

Namibia has only one domestic drug manufacturer and meets most of its demand for essential medicines through imports from other countries.[132] Importation is done through international competitive tenders, with a preference given to Namibian registered companies.[133] The Public Procurement Act of 2015 allows for this preference and allows Namibia to give a margin of preference to Namibian citizens, Namibian suppliers, and other companies that benefit Namibia (majority-owned by Namibia government or citizens, majority of net profits or benefits go back to Namibian citizens, joint venture registered in Namibia). Furthermore, the Act allows for Namibia to have exclusive preference for local suppliers.[134] Namibia is keen on building more internal capacity for drug manufacturing. However, given the understanding that economies of scale may not be achievable for in country manufacturers to lower drug prices, Namibia has encouraged both growth in regional manufacturing and shown interest and support to various pooled procurement mechanisms, such as regional vaccines and HIV related procurement.[135]

Namibia has a CMS that oversees drug procurement, storage, and distribution of medicines.[136] To ensure the quality of pharmaceutical commodities, the country also has a national regulatory institute, the Namibia Medicines Regulatory Council (NMRC) that regulates the use of medicines including medicine registration, quality assurance, and inspection.[137] Several policy changes have been undertaken to strengthen Namibia's drug procurement system. The National Drug Policy of 1998, also called the National Medicines Policy, outlines drug procurement in Namibia and establishes the NMRC.[138] In 2017, Systems for Improved Access to Pharmaceuticals and Services Namibia (SIAPS Namibia) helped the Ministry of Health and Social Services (MOHSS) revise this policy. This revision focused on improving efficiency of the drug supply chain and access to antiretroviral therapy (ART), particularly emphasizing tools like the MOHSS Pharmaceutical Dashboard, a monitoring and evaluation system for the National Medicines Policy, and access to medicines and rational use as key areas to focus on for efficiency gains.[139]

A key concern is that Namibia's CMS has struggled in procuring medicines at a low price; only 34 percent of the medicines on the tracer list are procured at a rate below the international benchmark.[140] Additionally, the fact that there is no provision for framework supply contracts means that the CMS is only able to procure limited quantities through requests for quotation (RFQ). The agency is often unable to meet the country's demand, leading to stockouts and understocks. Other organizations often step in to address these stockouts, for example USAID's Global Health Supply Chain Program Procurement and Supply Management (GHSC-PSM) has

[132] Verhage, 2012
[133] Ministry of Health and Social Services, "National Drug Policy for Namibia."
[134] Office of the Prime Minister Republic of Namibia, "Government Notice (Rep.)."
[135] Kapitako, A, "Namibia: Local Pharmaceutcial Companies Encouraged to Enter Regional Markets."
[136] Ministry of Health and Social Services, 1998
[137] About Us. (n.d.). Retrieved June 26, 2020, from http://BoMRA.nmrc.com.na/about
[138] Ministry of Health and Social Services, 1998
[139] Chevaux, Timothe, "SIAPS Namibia Provides Technical Assistance to Revise the National Medicines Policy – SIAPS Program."
[140] Verhage, 2012

processed multiple orders for pediatric ARVs in the past, due to stockouts.[141] An additional challenge that Namibia faces is a weak public tender system. Public tenders often face a long adjudication process with some requiring multiple reviews from the bid evaluation process. Inevitably, this drawn-out tender process leads to stockouts of essential medicines. Even when the tenders are completed in a timely manner, because Namibia's health sector has no consistent fixed supplier relationships (due to the lack of framework contracts), there is no guarantee that there will be a supplier able to fulfill the request.[142]

Due to the current national procurement challenges, Namibia has entered pooled procurement arrangements for some pharmaceutical commodities. Through PEPFAR's technical assistance, Namibia signed an agreement in 2019 on pooled procurement for vaccines with UNICEF that has a potential of USD 7 million savings. In the "Namibia Country Operational Plan (COP) 2020 Strategic Direction Summary," PEPFAR's commitment to helping Namibia with its high HIV burden is highlighted. In 2020, PEPFAR agreed to provide support on in-country procurement, particularly for medicines like pediatric ARVs, through framework contracts and pooled procurement mechanisms.[143] Namibia has also expressed interest in implementing different pooled procurement mechanisms. Former Minister of Health and Social Services of Namibia, Dr. Hautiku has been quoted saying, "The avenues are there already for pooled procurement. We can buy together but we still have to register products individually as countries."[144] While there have been regional efforts, as Dr. Hautiku points out, Namibia does have a gap around regional harmonization of drug regulations.

Looking at opportunities within regional coalitions, Namibia is a member of the Southern African Development Community (SADC). The SADC has made strides in harmonization in the region, setting up for opportunities to implement pooled procurement.[145] Namibia could do the same by joining the SADC Pooled Procurement Services (SPPS) which would facilitate pooled procurement within the region, yet it has not officially done so.[146]

SOUTH AFRICA

South Africa is an emerging pharmaceutical manufacturing market with 39 GMP Compliant manufacturers in the country, six of those affiliated with multinational pharmaceutical companies.[147,148] In 2014, South Africa imported USD 1.9 million worth of pharmaceutical

[141] USAID Global Health Supply Chain Program- Procurement and Supply Management (GHSC-PSM), "Fiscal Year 2018 Annual Report."
[142] Kapitako, "Namibia."
[143] "Namibia Country Operational Plan (COP) 2020 Strategic Direction Summary."
[144] Kapitako, A., 2018
[145] SADC, "Strategy for Pooled Procurement of Essential Medicines and Helath Commodities, 2013-2017."
[146] https://BoMRA.sadc.int/opportunities/procurement/open-procurement-opportunities/provision-voluntary-hosting-sadc-pooled-procurement-services-spps-medicines-and-health-commodities/
[147]Verhage, R. (2012, November). *SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study*.
[148] Tannoury and Attieh, "The Impact of Emerging Markets on the Pharmaceutical Industry."

products while exporting USD 380 million.[149] The top five destinations for South African pharmaceuticals are Zambia, Kenya, Zimbabwe, Ghana, and the United States[150]. When considering any regional procurement agreements, it is important to note that South Africa has strong protective measures for its in-country drug manufacturers and a preference for South African manufactured medicines.[151] The procurement system in South Africa is a two-stage system with price being the first stage. The second stage is a ten-point system with four points being awarded to local aspects, four points for Black Economic Empowerment (BEE), and two points to small and medium enterprises (SME).[152] However, international companies have worked around this by setting up small offices in South Africa that are BEE compliant, often winning contracts over larger local organizations.[153]

Drug procurement in South Africa is inextricably linked with its history. During apartheid, healthcare services, including procurement, were fragmented. Each of the then four provinces (Cape Province, Natal, Orange Free State and Transvaal) had their own CMS, Cape Province even had two. Each CMS oversaw distributing the medicines it procured, often not by needs or efficiency but rather by societal norms and biases. This led to further racial disparities as different medicines were available to different groups.[154]

After apartheid, a new constitution set up nine provinces, integrating former homelands. Each of these provinces oversaw their own fundamental services, included health services.[155] Two years post-apartheid, the South Africa National Drug Policy was established in 1996. There is now a National Department of Health and nine provincial departments of health, established by the constitution and National Health Act.[156] Currently, the National Department of Health is the national medical procurement agency, which operates through a national centralized tender process and the use of the National Essential Medicines List Committee (NEMLC).[157] In practice, the National Department of Health has contracts with suppliers on behalf of provincial depots. Once the contracts and tenders are rewarded, the provincial depots oversee the actual quantification, procurement, distribution, and warehousing of the products.[158,159]

With the adoption of a national tender process, South Africa lowered the procurement cost of medicines in the public sector. The procurement cost of medicines in the public sector was almost always lower than the procurement cost of medicines for the private sector. Healthcare services in the private sector are financed through medical aid schemes, covering about 17 percent of the

[149] IFMPMA, "Pharmaceutical Imports and Exports of Major African Countries in 2014."
[150] Verhage, 2012
[151] Verhage, 2012
[152]Naudé and Luiz, "An Industry Analysis of Pharmaceutical Production in South Africa."
[153] Maloney and Segal, "The Growth Potential of the Pharmaceuticals Sector in South Africa."
[154] Gray, Andy et al., "South Africa Implementation Fo Reforms under the National Drug Policy."
[155] Inman, Robert and Rubinfeld, Daniel, "Understanding the Democratic Transition in South Africa."
[156] Gray, Andy et al., "South Africa Implementation For Reforms under the National Drug Policy."
[157] Gray, A and Vawda, BOMRA., "South African Health Review 2017."
[158] Pharasi, B and Miot, J, "South African Health Review 2019."
[159] Berger, Johnathan et al., "Medicines Procurement Reform in the Public Sector."

population. The private sector does not use a tendering system to procure its medicines.[160] While the national tender process did seem to improve drug prices, it still has issues. Two issues identified with this procuring system were the discrepancies in forecasted need and items procured and shrinking diversity in firms who won the contracts.[161] Today, procurement in South Africa is still complex with centralized procurement for some medicines and decentralized procurement of others. Decentralization can bring more efficiency and more contextual based decisions, but it can also increase costs to individuals, decrease efficiency through standardization/uniformity, and national priorities not being met.[162] HIV, TB, and oncology are the focus areas for procurement in the country. Overall, the price disparity in medicines is not seen in what medicines are procured centrally or not, but rather what medicines are procured by the private sector versus the public sector, with the private sector paying more.[163]

While South Africa is not currently part of any pooled procurement agreements, it still has a unique position in the region with its manufacturing capabilities and large market size that could benefit from this type of procurement. As a supplier, South Africa could gain stability in aggregated demand through pooled procurement agreements and, as a result, reduced overall costs through achieving economies of scale.[164] South Africa has opportunities to share information about pricing and suppliers and potential in the future to participate in pooled procurement agreements. South Africa is a member of SADC where it could participate in the SADC Pooled Procurement Services (SPPS) with other member countries.[165] One risk that South Africa may be looking at when deciding to be part of pooled procurement agreements is its increased credit risk when going into these agreements as not all buyers may have a good track record of timely payments.[166]

With a complex and decentralized procurement system, South Africa may not be currently set up to procure its medicines from a regional pooled procurement agreement.[167,168] However, from a supplier perspective, South Africa may be interested in pooled procurement especially when this is driven by the regional platforms that the country participates in. For example, within the Southern Africa Customs Union countries like Eswatini are often encouraged to procure from South Africa due to the possibility of paying in local currencies.[169] Additionally, as a large country with challenges around access to medicines despite a large production capacity, South Africa may be interested in pooled procurement mechanisms, to ramp up local production because of access to larger markets. This stabilization of local manufacturing may lead to increased availability of

[160] Wouters et al., "The Impact of Pharmaceutical Tendering on Prices and Market Concentration in South Africa over a 14-Year Period."
[161] Wouters et al.
[162] Hendricks et al., "Decentralisation in South Africa."
[163] Dubois, P., Lefouili, BOMRA., & Straub, S., 2019
[164] Erickson, Elisa, "Research Synethesis: Pooled Procurement."
[165] SADC, "SADC, Tanzania Discuss SADC Pooled Procurement of Pharmaceuticals Services."
[166] Barbosa and Fiuza, "Demand Aggregation and Credit Risk Effects in Pooled Procurement."
[167] Gray, Andy et al., "South Africa Implementation Fo Reforms under the National Drug Policy."
[168] Gray, Andy et al.
[169] *SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study*.

essential medicines and decreased prices for South Africa and its partners in pooled procurement schemes.

TANZANIA

Tanzania produces less than 12 percent of its national demand for essential medicines through twelve pharmaceutical manufacturers, while the rest is imported from foreign countries, mainly, India and Kenya.[170] Tanzania has a strong emphasis on local production versus importing, particularly through its participation in the EAC which emphasizes building capacity for local production of essential medicines within the region.[171] Around 2004-2005, Tanzania's drug manufacturers were growing. It was expected that they would produce 30 percent of the total demand for medicines within Tanzania, while simultaneously exporting 10 percent of production. However, the manufacturers could not compete with the market price of imported medicines, nor could they reach efficient economies of scale in their production capacity.[172]

Before 1994, Tanzania used a CMS model to procure medicines, which meant that all medicines were procured and distributed by a centralized government unit. This was not financially sustainable and was changed with the 1992 Pharmaceutical Master Plan. The Plan set up autonomous Medical Stores Departments (MSDs) to procure essential medicines. The MSDs are government-owned but have their own rules and regulations. MSDs procure about 80 percent of essential medicines through competitive international bidding, 10 percent through selective bidding, and 5 percent through national competitive bidding.[173] Once procured, the MSDs oversee the distribution. They serve the public sector and mission-based or faith-based organizations. However, many hospitals and organizations procure their medicines via other sources because of the decentralization and the inability of the MSD to fulfill their requests.[174]

In 2004, Missions for Essential Medical Supplies (MEMS) ran a pilot program within Tanzania using pooled procurement in a pharmaceutical prime vendor system, which set a contracted price to customers grouped in a region. This ultimately failed due to MEMS underestimating the system's complexity and inability to meet contractual obligations and achieving low coverage.[175] A decade later, Jazia Prime Vendor began a pilot utilizing public-private partnership again with a prime vendor model and a pooled regional contract. The program has improved tracer medicine availability from 60 percent to 94 percent from 2014 to 2018. The program has succeeded due to its transparent and standardized procurement procedures. It is now being rolled out nationally across Tanzania to support the MSD procurement model.[176]

[170] Wande et al., "Pharmaceuticals Imports in Tanzania."
[171] East African Community, "2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027."
[172] Tibandebage et al., "Pharmaceutical Manufacturing Decline in Tanzania."
[173] Arney, Lesley et al., "Strategic Contracting Practices to Improve Procurement of Health Commodities."
[174] Mikkelsen-Lopez et al., "Essential Medicines in Tanzania."
[175] Wiedenmayer et al., "Jazia Prime Vendor System- a Public-Private Partnership to Improve Medicine Availability in Tanzania."
[176] Wiedenmayer et al.

In 2010, the World Bank Institute (WBI) launched the Improving Governance in Pharmaceutical Procurement and Supply Chain Management Initiative in Uganda, Kenya, and Tanzania. Over the next four years, this initiative formed a coalition with the Public Procurement Regulatory Authority to develop a procurement-monitoring tool and to determine compliance with the Public Procurement Act. In 2011, the Public Procurement Act gave preference to Tanzanian citizens or Tanzanian companies in the bidding process.[177] This initiative not only created capacity around public procurement within Tanzania, but also helped to emphasize transparency, accountability, and efficiency in procurement reforms.[178]

Tanzania has the systems in place (procurement agencies, list of essential medicines) to ensure access to essential medicines but has not yet seen improved outcomes around availability in the public sector. Some procurement challenges that Tanzania faced are a barrier to increasing not only availability but also access to underutilized funds due to delays in allocations, stockouts of medicines, and inflexibility on a system level to address delays.[179] The decentralization of the procurement system could help Tanzania in their journey to access with public procurement, as seen in the example with the Jazia Prime Vendor innovation. Additionally, Tanzania, along with other countries in the region, must look at strengthening its collective buying power with countries which are its key import partners given the setbacks faced around increasing internal production of essential medicines.[180] Tanzania signed an MOU in 2018 on the Provision of the SADC SPPS. Through this agreement, the country will share pricing and supplier information with other SADC member states. This agreement is expected to reduce pharmaceutical and medical supplies costs by 40 percent.[181]

[177] The United Republic of Tanzania, Public Procurement Act 2011.
[178] "Improving Governance in Pharmaceutical Procurement and Supply Chain Managent in Kenya, Tanzania and Ugaanda."
[179] Selvaraj, "Ensuring Access to Medicines in East Africa: Lessons from India."
[180] Selvaraj.
[181] SADC, "SADC, Tanzania Discuss SADC Pooled Procurement of Pharmaceuticals Services."